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As filed with the Securities and Exchange Commission on October 4, 2011

Registration No. 333-171300

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 4
to

FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NewLink Genetics Corporation
(Exact name of registrant as specified in its charter)

Delaware	**541700**	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2503 South Loop Drive
Ames, IA 50010
(515) 296-5555
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

CHARLES J. LINK, JR.
Chief Executive Officer
NewLink Genetics Corporation
2503 South Loop Drive
Ames, IA 50010
(515) 296-5555
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

James C.T. Linfield **Brent D. Fassett** **Cooley LLP** **380 Interlocken Crescent** **Broomfield, CO 80021** **(720) 566-4000**	**Geoffrey E. Liebmann** **Cahill Gordon & Reindel LLP** **Eighty Pine Street** **New York, NY 10005** **(212) 701-3000**

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Securities Exchange Act of 1934. (Check one):

Large Accelerated Filer o	Accelerated Filer o	Non-accelerated Filer ☒	Smaller Reporting Company o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.01 par value per share	$86,250,000	$6,150.00(3)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

(3) Previously paid.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 4, 2011

PROSPECTUS

Shares

Common Stock

$ per share

We are offering shares of our common stock. This is our initial public offering, and no public market currently exists for our common stock. We expect the initial public offering price to be between $ and $ per common share. We have applied to list our common stock on The NASDAQ Global Market under the symbol "NLNK."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 10.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public offering price	$	$
Underwriting discounts and commissions	$	$
Proceeds, before expenses, to NewLink Genetics Corporation	$	$

Delivery of the shares of common stock is expected to be made on or about , 2011. We have granted the underwriters an option for a period of 30 days to purchase, on the same terms and conditions set forth above, up to an additional shares of our common stock to cover overallotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Stifel Nicolaus Weisel **Canaccord Genuity**

Baird

The date of this prospectus is , 2011.

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You should rely only on the information contained in this prospectus and any related free writing prospectus we may authorize to be delivered to you. We have not, and the underwriters have not, authorized any person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. Neither this prospectus nor any related free writing prospectus is an offer to sell, nor are they seeking an offer to buy, these securities in any jurisdiction where the offer or solicitation is not permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus, and information may have changed since those dates.

For investors outside the United States: Neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

PROSPECTUS SUMMARY

The items in the following summary are described in more detail later in this prospectus. This summary does not contain all of the information you should consider. Before investing in our common stock, you should read the entire prospectus carefully, including the "Risk Factors" beginning on page 10, the "Business" section beginning on page 79, which more fully describes our product candidates and the status of our clinical trials and the financial statements and related notes beginning on page F-1. Unless the context indicates otherwise, as used in this prospectus, the terms "NewLink," "the Company," "we," "us" and "our" refer to NewLink Genetics Corporation.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. Our portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. Our product candidates use allogeneic (non-patient specific) cells from previously established cell lines rather than cells derived from the patient. We believe our approach enables a simpler, more consistent and scalable manufacturing process than therapies based on patient specific tissues or cells. Our lead product candidate, HyperAcute Pancreas cancer immunotherapy, or HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, according to the American Joint Committee on Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The clinical trial is being performed under a Special Protocol Assessment, or SPA, with the U.S. Food and Drug Administration, or FDA. We initiated this trial in May 2010 based on encouraging interim data from a 70-patient Phase 2 clinical trial in surgically-resected pancreatic cancer patients and have enrolled 161 patients at 52 clinical sites in the United States as of September 1, 2011. We plan to complete the first and second interim analyses of data from our Phase 3 clinical trial in late 2012 and 2013, respectively, and to complete enrollment in 2013. We have also received Fast Track and Orphan Drug designations from the FDA for HyperAcute Pancreas for the adjuvant treatment of surgically-resected pancreatic cancer.

We completed enrollment of our 70-patient Phase 2 clinical trial for HyperAcute Pancreas in surgically-resected pancreatic cancer in February 2010. In this open label, non-randomized trial, HyperAcute Pancreas was given in doses of either 100 million cells or 300 million cells approximately twice monthly for six months in combination with the standard-of-care treatment regimen, which consisted of gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. The interim data from this clinical trial indicate that HyperAcute Pancreas may improve disease-free and overall survival when given to patients in combination with standard-of-care following complete resection of detectable disease. As of May 10, 2011, all patients had reached at least 12 months of follow-up with a median follow-up period of approximately 21 months. The study met its primary objective with an established median disease free survival of 14.2 months. The most recent analyses of the secondary endpoint of overall survival showed one-year overall survival to be 86%. In addition, as of May 10, 2011, interim efficacy data for the 26 patients receiving high dose HyperAcute Pancreas immunotherapy demonstrated a median disease-free survival of 15.3 months and a one-year overall survival rate of 96%. HyperAcute Pancreas has also demonstrated a favorable safety profile to date.

The American Cancer Society has estimated that approximately 43,000 new cases of pancreatic cancer will be diagnosed in the United States in 2010. Pancreatic cancer has generally been recognized as an aggressive form of cancer that often remains undiagnosed in its earlier stages. As a result, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer

Society estimates one-year and five-year survival rates of 24% and 5%, respectively. HyperAcute Pancreas initially targets patients with localized tumors that can be removed surgically, or resected. According to eMedicine, a healthcare reference website run by WebMD containing peer-reviewed articles on diseases and medical topics, approximately 20% of patients in the United States are eligible for resection at initial diagnosis. These earlier stage, resected patients have significantly better prognoses than patients with later-stage disease since they tend to have better nutritional and immune status and significantly lower amounts of micro-metastatic and residual disease. A study published in the *Journal of the American Medical Association* showed that resection followed by chemotherapy or chemoradiotherapy, known as adjuvant therapy, extends median survival to approximately 18 months. We believe the addition of HyperAcute Pancreas to adjuvant standard-of-care has the potential to improve median disease-free survival and overall survival in resected pancreatic cancer patients.

In addition to HyperAcute Pancreas, we and our collaborators have completed patient enrollment for a Phase 1/2 clinical trial evaluating our HyperAcute Lung cancer immunotherapy product candidate, or HyperAcute Lung, for non-small cell lung cancer, or NSCLC, and a Phase 2 clinical trial for our HyperAcute Melanoma cancer immunotherapy product candidate, or HyperAcute Melanoma. In the Phase 1/2 single arm, open label HyperAcute Lung clinical trial, we administered our product candidate as a monotherapy in 54 patients with refractory, recurrent or metastatic nonresectable NSCLC. In the Phase 2 portion, the 28 patients evaluated for clinical response received injections of 300 million cells every two weeks for up to eight doses. We performed an interim analysis of the 28 patients on December 9, 2010, which showed median overall survival of 11.3 months and a one-year survival rate of 46%. Based on our analysis of data from comparable precedent clinical trials of similar patients, we would have expected a median overall survival of approximately eight months. In an interim analysis of 45 patients, HyperAcute Lung demonstrated a favorable safety profile and no dose limiting toxicities. We are conducting this Phase 1/2 study at the National Cancer Institute, or NCI. We anticipate initiating a Phase 2B/3 clinical trial in advanced NSCLC patients in the first half of 2012 and completing the first interim analysis in 2013.

HyperAcute Melanoma is being studied in an investigator-initiated, fully-enrolled 25-patient Phase 2 clinical trial for the treatment of advanced melanoma in combination with an eight-week course of PEG-Intron, a man-made immune modulator. The treatment consists of 12 weekly injections of HyperAcute Melanoma with PEG-Intron being co-administered in weeks five through 12. As of September 8, 2011, interim analysis shows encouraging results, with all of the patients developing low levels of autoimmune antibodies and four out of 25 of the patients developing vitiligo, an autoimmune condition in which the patient's immune system attacks melanoctyes in the skin. In previous melanoma immunotherapy studies, vitiligo has been correlated with favorable response to therapy. HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile to date. We anticipate announcing the results from this trial in the second half of 2011. We anticipate initiating a Phase 2B clinical trial in melanoma in 2012.

Our HyperAcute Pancreas, Lung and Melanoma product candidates are based on our HyperAcute immunotherapy technology, which is designed to stimulate the human immune system by exploiting a natural barrier present in humans that protects against infection being transmitted from other mammals. This barrier is related to the enzyme, alpha (1,3) galactosyl transferase, or a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or a-Gal, on the surface of affected cells. Introducing a-Gal expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal. Antibodies directed against the a-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

Our HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is

present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti-a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens common to both the immunotherapy and the patient's tumor cells.

In addition to our HyperAcute product candidates, we are developing d-1-methyltryptophan, or D-1MT, a small-molecule, orally bioavailable product candidate from our proprietary indoleamine-(2,3)-dioxygenase, or IDO, pathway inhibitor technology. In preclinical models, IDO pathway inhibitors have shown anti-tumor effects in combination with radiotherapy, chemotherapy, targeted therapy or immunotherapy. Through our collaboration with the NCI, we are studying D-1MT in various chemotherapy and immunotherapy combinations in two Phase 1B/2 safety and efficacy clinical trials. The first clinical trial has primary endpoints that assess the safety and efficacy of D-1MT in combination with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The second clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with Taxotere® for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. We anticipate announcing preliminary data from these trials by the end of 2011.

Investment Highlights

We believe the following are the key attributes of our company:

- Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial based on encouraging interim Phase 2 survival data in surgically-resected pancreatic cancer patients.
- Our novel HyperAcute technology has a wide range of anti-cancer applications including two additional product candidates, HyperAcute Lung and HyperAcute Melanoma, in active clinical development.
- We have in-house manufacturing capabilities for our HyperAcute product candidates that we believe are sufficient to support clinical development and initial commercialization of HyperAcute Pancreas in the United States.
- Our lead IDO pathway inhibitor product candidate is in clinical development in combination with multiple alternative therapies, including Taxotere.
- We have an extensive intellectual property portfolio.

Our Strategy

Our strategy is to discover, develop and commercialize immunotherapeutic products for the treatment of cancer where the needs of patients are unmet by current therapies. The critical components of our business strategy include:

- Complete the Phase 3 clinical trial of HyperAcute Pancreas, our lead immunotherapy product candidate, and gain regulatory approval.
- Develop sales and marketing infrastructure to commercialize our HyperAcute Pancreas product candidate in the United States and establish commercial partnerships in other regions.
- Advance our HyperAcute Lung and HyperAcute Melanoma product candidates through additional clinical trials.
- Expand our manufacturing capabilities for our HyperAcute immunotherapy product candidates.
- Investigate our HyperAcute immunotherapy technology in additional oncology indications.
- Develop and commercialize D-1MT, our small-molecule product candidate, for the treatment of various oncology indications.

Our Risks

We are a development stage biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in "Risk Factors" beginning on page 10:

- To date, we have not completed clinical development for any of our products candidates and we do not have a product candidate that has been approved for sale by the FDA.
- Our near term prospects are highly dependent on HyperAcute Pancreas. If we fail to demonstrate efficacy in clinical trials, fail to obtain regulatory approval or fail to successfully commercialize HyperAcute Pancreas, our business would be harmed and the value of our securities would likely decline.
- If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not tested any of our product candidates in controlled clinical trials.
- Our HyperAcute product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our product candidates.
- While we have negotiated an SPA with the FDA relating to our HyperAcute Pancreas Phase 3 clinical trial, the SPA does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.
- We may face delays in completing our clinical trials and we may not be able to complete them at all.
- Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.
- Our product candidates are being and will be studied in clinical trials co-sponsored by the NCI and in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.
- We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.
- As of June 30, 2011, we had $6 million in outstanding debt under a forgivable loan agreement with the Iowa Department of Economic Development, of which $4.7 million may be accelerated and require repayment as early as March 18, 2012.
- Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.
- We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.
- We replicate all biological cells for our products internally and utilize a single manufacturing site to manufacture our clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing and would result in delays, increased costs or losses.
- The industry within which we operate and our business are subject to extensive regulation, which is costly, time consuming and may subject us to unanticipated delays.
- We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.
- If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.
- We have a history of net losses, including net losses of $8.3 million, $16.2 million and $10.0 million for the six months ended June 30, 2011, and the years ended December 31, 2010 and December 31,

2009, respectively. As of June 30, 2011, we had an accumulated deficit of $71.7 million. We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

- We will require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Corporate Information

We were incorporated as NewLink Genetics Corporation in Delaware on June 4, 1999. Our principal executive offices are located at 2503 South Loop Drive, Ames, IA 50010, and our telephone number is (515) 296-5555. Our website address is *www.linkp.com*. The information contained in or that can be accessed through our website is not part of this prospectus.

HyperAcute® and NewLink Genetics® are registered trademarks of ours. Other trademarks and tradenames set forth herein are property of their respective owners. Registered trademarks and tradenames will be accompanied by the "®" designation only on their first reference.

The Offering

Common stock offered	shares (or shares if the underwriters' overallotment option is exercised in full).
Common stock to be outstanding after this offering	shares (or shares if the underwriters' overallotment option is exercised in full).
Use of proceeds	We intend to use the net proceeds from this offering to fund clinical trials and other research and development activities for HyperAcute Pancreas, our other HyperAcute immunotherapy product candidates and our IDO pathway inhibitor product candidate and for working capital and other general corporate purposes.
Risk factors	You should read the "Risk Factors" section of this prospectus beginning on page 10 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Global Market symbol	NLNK

The number of shares of common stock to be outstanding after this offering is based on shares of common stock outstanding as of June 30, 2011, after giving effect to the conversion of all our outstanding shares of preferred stock into shares of common stock upon the completion of this offering, and excludes:

- 1,164,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Equity Incentive Plan, or 2000 Plan, as of June 30, 2011 having a weighted average exercise price of $0.90 per share;
- 5,349,895 shares of common stock issuable upon the exercise of outstanding options under our 2009 Equity Incentive Plan, as amended, or 2009 Plan, as of June 30, 2011 having a weighted average exercise price of $1.50 per share, which includes 106,078 shares of common stock issuable upon the exercise of options that were issued in connection with our acquisition of the minority interest in BioProtection Systems Corporation, or BPS, in exchange for outstanding options to purchase the Series B common stock of BPS;

- 1,535,986 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation—Employee Benefit Plans—2009 Equity Incentive Plan" of this prospectus, of which 887,500 shares of common stock are issuable upon the exercise of options that have been approved by the Company's Board of Directors through July 29, 2011 and will be granted effective concurrently with the completion of this offering or as of December 31, 2011, if later; and
- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering.

Unless otherwise noted, the information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock into shares of common stock upon the completion of this offering;
- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws upon the completion of this offering;
- no exercise of the underwriters' over-allotment option; and
- a one-for- reverse stock split of our common stock to be effected before completion of this offering.

The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a $1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

Summary Financial Data

The following tables summarize certain of our financial data. The summary statement of operations data for the years ended December 31, 2008, 2009 and 2010 are derived from our audited financial statements included elsewhere in this prospectus. The summary statement of operations data for the six months ended June 30, 2010 and 2011 and the balance sheet data as of June 30, 2011 have been derived from our unaudited interim financial statements, which are included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, consisting primarily of normal recurring adjustments, necessary to fairly present our financial position as of June 30, 2011, and the results of operations for the six months ended June 30, 2010 and 2011. Our historical results of operations and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future. The summary financial data set forth below should be read together with our financial statements and related notes, "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	Years Ended December 31,			Six Months Ended June 30,	
	2008	2009	2010	2010	2011
	(in thousands, except per share data)			(unaudited)	(unaudited)
Statement of operations data:					
Grant revenue	$ 633	$ 934	$ 2,079	$ 730	$ 1,141
Operating expenses:					
Research and development(1)	5,790	7,578	12,666	5,696	6,975
General and administrative(1)	3,938	3,705	6,074	2,284	2,452
Total operating expenses	9,728	11,283	18,740	7,980	9,427
Loss from operations	(9,095)	(10,349)	(16,661)	(7,250)	(8,286)
Other income and expense:					
Miscellaneous income	42	19	71	8	1
Interest income	213	132	75	23	8
Interest expense	(2)	(9)	(47)	(19)	(15)
Other income, net	253	142	99	12	(6)
Net loss	(8,842)	(10,207)	(16,562)	(7,238)	(8,292)
Less net loss attributable to noncontrolling interest(2)	—	233	349	151	1
Net loss attributable to NewLink	$ (8,842)	$ (9,974)	$ (16,213)	$ (7,087)	$ (8,291)
Net loss per share-basic and diluted	$ (1.35)	$ (1.50)	$ (2.30)	$ (1.06)	$ (1.08)
Weighted average shares outstanding—basic and diluted	6,542	6,636	7,040	6,710	7,647
Pro forma as adjusted net loss per share—basic and diluted (unaudited)(3)			$		$
Weighted average pro forma as adjusted shares outstanding (unaudited)(3)					

	As of June 30, 2011		
	Actual	(unaudited) Pro Forma	Pro Forma As Adjusted
		(in thousands)	
Balance sheet data:			
Cash, cash equivalents, and certificates of deposit	$ 9,800	$ 9,800	
Working capital	3,255	3,255	
Total assets	17,315	17,315	
Notes payable and obligations under capital leases	7,260	7,260	
Convertible preferred stock	76,302	—	
Deficit accumulated during the development stage	(71,680)	(71,680)	
Total (deficit) equity	$ (67,845)	$ 7,427	

(1) Research and development and general and administrative expenses were corrected for misclassification and immaterial errors in 2008, 2009 and 2010. See note 3 in the notes to the consolidated financial statements included in this prospectus.

(2) Further explanation is described under the caption "Noncontrolling Interest" in note 2(o) to the consolidated financial statements included in this prospectus.

(3) Pro forma as adjusted net loss per share and weighted average pro forma as adjusted shares outstanding assume the conversion of all our outstanding convertible preferred stock into an aggregate of shares of common stock as of January 1, 2010.

The summary pro forma and pro forma as adjusted balance sheet data above gives effect to the following transactions as if they had occurred as of June 30, 2011:

- on a pro forma basis (i) the issuance of 55,238 shares of Series E preferred stock in connection with our acquisition of the minority interest in our majority owned subsidiary, BPS, which were issued on August 12, 2011 after the closing of the acquisition and (ii) the conversion of all of our outstanding convertible preferred stock into an aggregate of shares of common stock, which will take place automatically upon the closing of this offering in accordance with the terms of our preferred stock; and
- on a pro forma as adjusted basis the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and certificates of deposit, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of

common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a $1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

The table above does not include:

- 1,164,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Plan, as of June 30, 2011 having a weighted average exercise price of $0.90 per share;
- 5,349,895 shares of common stock issuable upon the exercise of outstanding options under our 2009 Plan as of June 30, 2011 having a weighted average exercise price of $1.50 per share, which includes 106,347 shares of common stock issuable upon the exercise of options that were issued in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS;
- 1,535,986 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation—Employee Benefit Plans—2009 Equity Incentive Plan" section of this prospectus, of which 887,500 shares of common stock are issuable upon the exercise of options that have been approved by the Company's Board of Directors through July 29, 2011 and will be granted effective concurrently with the completion of this offering or as of December 31, 2011, if later; and
- 950,000 shares of common stock reserved for future issuance under our Directors' Plan and 2010 Purchase Plan, each of which will become effective upon the completion of this offering.

RISK FACTORS

Investing in our common stock involves a high degree of risk. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve risks and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

Our near term prospects are highly dependent on HyperAcute Pancreas. If we fail to complete, or demonstrate safety and efficacy in, clinical trials, fail to obtain regulatory approval or fail to successfully commercialize HyperAcute Pancreas, our business would be harmed and the value of our securities would likely decline.

We must be evaluated in light of the uncertainties and complexities affecting a development stage biopharmaceutical company. We have not completed clinical development for any of our products. Our most advanced product candidate is HyperAcute Pancreas. The United States Food and Drug Administration, or FDA, must approve HyperAcute Pancreas before it can be marketed or sold. Our ability to obtain FDA approval of HyperAcute Pancreas depends on, among other things, completion of our Phase 3 clinical trial, whether our Phase 3 clinical trial of HyperAcute Pancreas demonstrates statistically significant achievement of the clinical trial endpoints with no significant safety issues and whether the FDA agrees that the data from our Phase 3 clinical trial of HyperAcute Pancreas is sufficient to support approval. The final results of our Phase 3 clinical trials of HyperAcute Pancreas may not meet the FDA's requirements to approve the product for marketing, and the FDA may otherwise determine that our manufacturing processes, facilities or raw materials are insufficient to warrant approval. We may need to conduct more clinical trials than we currently anticipate. Furthermore, even if we do receive FDA approval, we may not be successful in commercializing HyperAcute Pancreas. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

If our product candidates do not meet safety and efficacy endpoints in clinical trials, they will not receive regulatory approval, and we will be unable to market them. We have not tested any of our product candidates in controlled clinical trials.

The clinical development and regulatory approval process is expensive and time-consuming. The timing of any future product approval cannot be accurately predicted. If we fail to obtain regulatory approval for our current or future product candidates, we will be unable to market and sell them and therefore we may never be profitable.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints.

In particular, there have been no control groups in our clinical trials conducted to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of our HyperAcute Pancreas product candidate, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared. As a result, we are studying HyperAcute Pancreas in combination with the current standard-of-care in direct comparison to the current standard-of-care alone in the same trial and will need to show a statistically significant benefit when added to the current standard-of-care in order for HyperAcute Pancreas to be approved as a marketable drug. Patients in our Phase 3 study who do not receive HyperAcute Pancreas may not have results similar to patients studied in the other studies we have used for comparison to our Phase 2 studies. If the patients in our Phase 3 study who receive standard-of-care without HyperAcute Pancreas have results which are better than the results predicted by the other large studies, we may not demonstrate a sufficient benefit from the HyperAcute Pancreas to allow the FDA to approve it for marketing.

Our HyperAcute product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval or personnel issues that may keep us from being able to develop our product candidates.

Our HyperAcute product candidates are based on our novel HyperAcute immunotherapy technology. In the course of developing this technology and these product candidates, we have encountered difficulties in the development process. There can be no assurance that additional development problems will not arise in the future which we may not be able to resolve or which may cause significant delays in development.

Regulatory approval of novel product candidates such as ours can be more expensive and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to our and regulatory agencies' lack of experience with them. This may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. For example, the two cell lines that comprise HyperAcute Pancreas are novel and complex therapeutics that we have endeavored to better characterize so that their identity, strength, quality, purity and potency may be compared among batches created from different manufacturing methods. We currently lack the manufacturing capacity necessary for larger-scale production. If we make any changes to our current manufacturing methods or cannot design assays that satisfy FDA's expectations regarding the equivalency of such therapeutics in the laboratory, the FDA may require us to undertake additional clinical trials.

The novel nature of our product candidates also means that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel for research, development and manufacturing positions.

Our Special Protocol Assessment, or SPA, with the FDA relating to our HyperAcute Pancreas Phase 3 clinical trial does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.

The protocol for our HyperAcute Pancreas Phase 3 clinical trial was reviewed by the FDA under its SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a New Drug Application, or NDA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval, the FDA retains the right to require additional Phase 3 testing and we cannot be certain that the design of, or data collected from, the HyperAcute Pancreas Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of HyperAcute Pancreas for the treatment of patients with pancreatic cancer, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition, the survival rates, duration of response and

safety profile required to support FDA approval are not specified in the HyperAcute Pancreas Phase 3 clinical trial protocol and will be subject to FDA review. Although the SPA agreement calls for review of interim data at certain times prior to completion, there is no assurance that any such review, even if such interim data is positive, will result in early approval. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the HyperAcute Pancreas Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the HyperAcute Pancreas Phase 3 clinical trial, or whether HyperAcute Pancreas will receive any regulatory approvals as a result of the SPA agreement or the HyperAcute Pancreas Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for HyperAcute Pancreas for the treatment of patients with pancreatic cancer.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle including by allowing Investigational New Drug applications, or INDs, to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. If we do not accurately evaluate the scientific and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

We may face delays in completing our clinical trials, and we may not be able to complete them at all.

We have not completed all the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- slower than expected patient enrollment or lack of a sufficient number of patients that meet the enrollment criteria for our clinical trials;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;

- product candidates may demonstrate a lack of efficacy during clinical trials;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in achieving study endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for the HyperAcute product candidates, D-1MT or other product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize the HyperAcute product candidates, D-1MT or other future product candidates will be adversely affected.

If we encounter difficulties enrolling patients in our clinical trials, our clinical trials could be delayed or otherwise adversely affected.

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events for reasons that may not be related to the product candidate we are testing or, in those trials where our product candidate is being tested in combination with one or more other therapies, for reasons that may be attributable to such other therapies, but which can nevertheless negatively affect clinical trial results. In addition, we have experienced difficulties enrolling patients in certain of our smaller clinical trials due to lack of referrals and may experience similar difficulties in the future.

If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous

guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA; should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

The FDA and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional work on our part.

Any delay in, or failure to receive or maintain, approval for any of our product candidates could prevent us from ever generating meaningful revenues or achieving profitability.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Clinical trials must be conducted in accordance with the FDA's current Good Clinical Practices, or cGCP, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practices, or cGMP, and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial

protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our HyperAcute product candidates, D-1MT and other product candidates could take a significantly longer time to gain regulatory approval for any additional indications than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating the commercialization of our HyperAcute product candidates, D-1MT and other product candidates for additional indications.

Our product candidates are being and will be studied in clinical trials co-sponsored by the National Cancer Institute, or NCI, and in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

Our D-1MT product candidate is being studied in a two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are also currently providing clinical supply of our HyperAcute Melanoma product candidate in support of a Phase 2 investigator-initiated clinical trial. We expect to continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

If we cannot demonstrate the safety of our product candidates in preclinical and/or other non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for our product candidates.

In order to move a product candidate not yet being tested in humans into a clinical trial, we must first demonstrate in preclinical testing that the product candidate is safe. Furthermore, in order to obtain approval, we must also demonstrate safety in various preclinical and non-clinical tests. We may not have conducted or may not conduct in the future the types of preclinical and other non-clinical testing ultimately required by regulatory authorities, or future preclinical tests may indicate that our product candidates are not safe for use in humans. Preclinical testing is expensive, can take many years and have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- our product candidates may have unfavorable pharmacology, toxicology or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operations.

Even if approved, the HyperAcute product candidates, D-1MT or any other product we may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory, the FDA or a comparable agency in a foreign country may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to fulfill. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our products.

We will need to develop or acquire additional capabilities in order to commercialize any product candidates that obtain FDA approval, and we may encounter unexpected costs or difficulties in doing so.

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have no experience in preparing applications for marketing approval, commercial-scale manufacturing, managing of large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- train, manage and motivate a growing employee base;
- accurately forecast demand for our products; and
- expand existing operational, financial and management information systems.

We plan to increase our manufacturing capacity and seek FDA approval for our production process simultaneously with seeking approval for sale of our HyperAcute Pancreas product candidate. Should we not receive timely approval of our production process, our ability to produce the immunotherapy products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate significant product revenue.

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we market and sell any products that we develop ourselves.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales,

marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

Because the establishment of sales, marketing and distribution capabilities depends on the progress towards commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to partner with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff, particularly Dr. Charles J. Link, Jr. The loss of his services might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit a significant number of additional personnel in order to achieve our operating goals. In order to pursue our product development and marketing and sales plans, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. If the personnel that have contingently agreed to join us do not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our facilities are located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. We have two forgivable loans totaling $6.4 million that are contingent on us creating jobs in Iowa. If we leave Iowa or fail to create the required number of jobs in Iowa, we may be required to pay back some or all of those loans. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing Activities

We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have no experience in commercial-scale manufacturing, the management of large-scale information technology systems or the management of a large-scale distribution system. We may develop our manufacturing capacity in part by expanding our current facilities. This activity would require

substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are sufficient to produce materials for additional later-stage clinical trials or commercial use.

If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of our Biologics License Application, or BLA, or New Drug Application, or NDA, on a timely basis and must adhere to Good Laboratory Practice, or GLP and cGMP regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA approval of the products will not be granted.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products.

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our existing contract manufacturer for D-1MT and the components used in the HyperAcute product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of the HyperAcute product candidates, D-1MT or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of the HyperAcute product candidates, D-1MT or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

We currently rely on relationships with third-party contract manufacturers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates in the near-term.

We will rely upon contract manufacturers for D-1MT, and for components of the HyperAcute product candidates, for commercial sale if any are approved for sale. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of antigen, components or finished HyperAcute product candidates or D-1MT. This could delay or reduce commercial sales and materially harm our business. We do not currently have experience with the manufacture of products at commercial scale, and may incur substantial costs to develop the capability to manufacture products at commercial scale. Any prolonged delay or interruption in the operations of our facilities or our contract manufacturers' facilities could result in cancellation of

shipments, loss of components in the process of being manufactured or a shortfall in availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in regulatory requirements or standards that require modifications to our manufacturing processes, action by the regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of drug substances could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to timely meet market demand for any products that are approved for sale.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research and development involves the controlled use of hazardous materials, chemicals, various active microorganisms and volatile organic compounds, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the Drug Enforcement Agency, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Food, Drug and Cosmetic Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our product candidates, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials, and for killing any unused microorganisms before disposing of them, comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

We replicate all biological cells for our products internally and utilize a single manufacturing site to manufacture our clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing and would result in increased costs and losses.

We have thus far elected to replicate all biological cells for our products internally using a complex process. The disruption of our operations could result in manufacturing delays due to the inability to purchase the cell lines from outside sources. We have only one manufacturing facility in which we can manufacture clinical products. In the event of a physical catastrophe at our manufacturing or laboratory facilities, we could experience costly delays in reestablishing manufacturing capacity, due to a lack of redundancy in manufacturing capability.

Our current manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming and costly to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. We may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as

natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

We recently transferred our manufacturing operation to a new facility. We have experienced bacterial and mycoplasm contaminations in lots produced at the previous facility and we destroyed the contaminated lots and certain overlapping lots. We may have contaminated lots at our new facility and we will destroy any contaminated lots that we detect.

Our facilities are located in areas where floods and tornados are known to occur, and the occurrence of a flood, tornado or other catastrophic disaster could damage our facilities and equipment, which could cause us to curtail or cease operations.

Our facilities are located in Ames, Iowa, which is susceptible to floods and tornados, and our facilities are therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business personal property insurance in the amount of $6.25 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Risks Relating to Regulation of Our Industry

The industry within which we operate and our business are subject to extensive regulation, which is costly, time consuming and may subject us to unanticipated delays.

The research, design, testing, manufacturing, labeling, marketing, distribution and advertising of biologic and pharmaceutical products such as our product candidates are subject to extensive regulation by governmental regulatory authorities in the United States and other countries. The drug development and approval process is generally lengthy, expensive and subject to unanticipated delays. Data obtained from preclinical and clinical testing are subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, delays or rejections may be encountered based upon changes in regulatory policy for product approval during the period of development and regulatory review of each submitted application for approval. To obtain approval for a product candidate, we must demonstrate to the satisfaction of the regulatory authorities that the product candidate is safe, pure, potent and effective, which typically takes several years or more depending upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. There can be no assurance that we will not encounter problems in clinical trials that would cause us or the regulatory authorities to delay or suspend clinical trials. Any such delay or suspension could have a material adverse effect on our business, financial condition and results of operations.

There can be no assurance that clinical studies for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. There can be no assurance that we will not encounter problems in clinical trials that will cause us to delay or suspend clinical trials.

Regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate. To date, the FDA has approved only one active cellular cancer immunotherapy product, even though several have been, and currently are in, clinical development. Further, even if such regulatory approval is obtained, we, our

products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer.

We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. Once we submit our potential products for review, there can be no assurance that regulatory approvals for any pharmaceutical products developed by us will be granted on a timely basis, if at all.

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and NDA. A delay in obtaining or failure to obtain such approvals would have a material adverse effect on our business, financial condition and results of operations. Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record keeping and reporting of adverse experiences and other information. In addition, we would be required to comply with federal and state anti-kickback and other health care fraud and abuse laws that pertain to the marketing of pharmaceuticals. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Non-compliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payors may reimburse for our potential product, are uncertain.

In both United States and foreign markets, sales of our proposed products will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.

In addition, in both the United States and elsewhere, sales of prescription drugs are dependent in part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that our proposed products will be considered cost-effective or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. As a result, we may elect not to market future products in certain markets.

Moreover, while we are in clinical trials, we will not be reimbursed for any of our materials used during the clinical trials.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing.

In addition to FDA restrictions on marketing of biopharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and

state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

Multi-jurisdictional regulations, including those establishing our ability to price products, may negatively affect our sales and profit margins.

We expect to face pricing pressure globally from managed care organizations, institutions and government agencies and programs, which could negatively affect the sales and profit margins for our HyperAcute product candidates, D1-MT or any other of our product candidates that are approved for marketing. For example, in the United States, the Medicare Modernization Act contains a prescription drug benefit for individuals who are eligible for Medicare. The prescription drug benefit became effective on January 1, 2006 and has resulted in increased use of generics and increased purchasing power of those negotiating on behalf of Medicare recipients, which in turn may result in increased pricing pressure on our products.

Health care reform measures could adversely affect our business.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. Most recently, in March 2010 the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;
- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending beginning by January 1, 2011.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA to our HyperAcute product candidates. The FDA is only now soliciting public comment and conducting hearings to assist them in drafting regulations under the PPACA. It is not certain that we will receive 12 years of

marketing exclusivity for any of our products. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Financial Risks

We have a history of net losses. We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

We are not profitable and have incurred significant net losses in each year since our inception, including net losses of $8.3 million, $16.2 million, $10.0 million and $8.8 million for the six months ending June 30, 2011, and the years ended December 31, 2010, 2009 and 2008, respectively. As of June 30, 2011, we had an accumulated deficit of $71.7 million. Our losses have resulted principally from costs incurred in our discovery and development activities. We anticipate that our operating losses will substantially increase over the next several years as we expand our discovery, research and development activities, including the Phase 2 and Phase 3 clinical development of the HyperAcute product candidates and Phase 2 clinical development of D-1MT.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities, government grants, economic development loans and capital lease and equipment financing. The size of our future net losses will depend, in part, on the rate of growth or contraction of our expenses and the level and rate of growth, if any, of our revenues. Our ability to achieve profitability is dependent on our ability, alone or with others, to complete the development of our products successfully, obtain the required regulatory approvals, manufacture and market our proposed products successfully or have such products manufactured and marketed by others and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability.

We will require substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

Development of our HyperAcute product candidates, D-1MT and any other product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any future strategic partnerships.

We anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, develop our pipeline and expand our corporate infrastructure. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will allow us to fund our operating plan through at least the end of 2012. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from around $200,000 to $2.8 million per license (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors are subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

We may never be able to generate a sufficient amount of product revenue to cover our expenses. Until we do, we expect to seek additional funding through public or private equity or debt financings, collaborative relationships, capital lease transactions or other available financing transactions. However, there can be no assurance that additional financing will be available on acceptable terms, if at all, and such financings could be dilutive to existing stockholders. Moreover, in the event that additional funds are obtained through arrangements with collaborative partners, such arrangements may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. Our failure to obtain adequate financing when needed and on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

We have outstanding debt which may be accelerated as early as March 18, 2012.

In March 2005, we entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDED. The project is to provide us with financial assistance for research and product development activities at our Iowa State University Research Park facility. The project calls for the creation of 315 jobs at the time of commercialization and retention of 35 jobs with total project expenditures of $189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs. As of June 30, 2011, we believe we had created 43 jobs, retained 35 jobs and incurred $70.5 million of project expenditures. If, as of March 18, 2012, the IDED determines we have fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date we will be required to repay the greater of either approximately $17,000 for each of the 350 jobs we fail to create and maintain as of that date or a percentage of the $6.0 million advanced under the agreement equal to the percentage of any shortfall in our obligation to expend $189.9 million of project expenditures. Five years following the project completion date, we will be required to repay approximately $17,000 for each of the 350 jobs the IDED determines we failed to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6% interest per annum beginning at the date of default. We are also obligated to maintain our business in the State of Iowa while amounts remain outstanding under this loan.

We have not currently fulfilled the requirements for loan forgiveness under this agreement. Absent an amendment granted by the IDED, we would have to repay up to $4.7 million on or after March 18, 2012. There is no guarantee that the IDED will agree to further extend the completion date under the agreement. If the amounts under the loan become due in March 2012, it would likely have a material adverse affect on our cash position. Additionally, under the agreement, we are obligated to pay a minimum

of 0.25% royalties on all gross revenues of any products we bring to market with a cumulative maximum royalty amount due of $3.2 million. Substantially all of our assets are pledged to secure this loan.

In March 2010, we entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, in order to help finance the construction of new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015. The project calls for us to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or retain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for us to enter into a five-year building lease with option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, we have failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, we will be required to repay approximately $3,100 per job not created or retained following the respective date. As of June 30, 2011, we had created or retained an aggregate of 76 full-time jobs in Ames, Iowa. As of June 30, 2011, $300,000 of the total $400,000 forgivable loan was advanced to us with the final $100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6.5% interest per annum beginning at the date of default.

We have not met the full job creation requirements of these loans as of the present date. If we cannot or do not comply with these and all other requirements under these loans, we may be obligated to pay principal and interest on these loans immediately. If we are unable to meet our obligations to service our debt and fund our business, we may be forced to reduce or delay capital expenditures, seek additional debt financing or equity capital, restructure or refinance our debt or sell assets. We cannot assure you that we would be able to obtain additional financing, refinance existing debt or sell assets on satisfactory terms or at all.

Even though we have received governmental support in the past, we may not continue to receive support at the same level or at all.

We have received significant financial assistance from state and local governments, primarily in the form of forgivable loans. There can be no assurance that we will continue to receive the same level of assistance from these or other government agencies, if at all.

Through our subsidiary, BioProtection Systems Corporation, or BPS, we also have ongoing contracts and grants with the United States Department of Defense and National Institutes of Health, respectively. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Risks Relating to Competitive Factors

We compete in an industry characterized by extensive research and development efforts and rapid technological progress. New discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.

New developments occur and are expected to continue to occur at a rapid pace, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive, which would have a material adverse effect on our business, financial condition and results of operations.

We expect to compete with fully integrated and well-established pharmaceutical and biotechnology companies in the near and long term. Most of these companies have substantially greater financial, research and development, manufacturing and marketing experience and resources than we do and represent substantial long-term competition for us. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

We will face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

There can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide us with proprietary protection or a competitive advantage.

Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success of any products we may commercialize.

The biopharmaceutical industry is highly competitive. There are many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. Given the significant unmet patient need for new therapies, oncology is an area of focus for large and small companies as well as research institutions. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates, and several large public biopharmaceutical companies have approved or are developing cancer immunotherapy products, including Dendreon Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline plc, Merck & Co., Merck KGaA and Sanofi-Aventis.

There are several marketed products indicated for pancreatic cancer, including Eli Lilly and Company's Gemzar®, Astellas Pharma's Tarceva®, Teva Pharmaceutical Industries Limited's streptozocin, and fluorouracil, or 5-FU, and mitomycin which are marketed by several generic pharmaceutical firms. There are numerous marketed therapeutics indicated for NSCLC, including Roche AG's Avastin®, Eli Lilly's Alimta® and Gemzar, Astellas Pharma's Tarceva, AstraZeneca's Iressa®, and Sanofi-Aventis' Taxotere and Eloxatin, as well as generically available platinum-based chemotherapeutics (cisplatin and carboplatin) and mitotic inhibitors (paclitaxel and venorelbine). There are also several marketed therapeutics indicated for advanced melanoma, including Merck's Intron A and Novartis/Prometheus Laboratories' Proleukin®, as well as cisplatin and dacarbazine, which are available generically. Bristol-Myers Squibb's immunotherapy ipilimumab was recently approved by the FDA as was Roche/Daiichi Sankyo's drug, vemurafenid.

In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer including AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics Inc., Sanofi-Aventis and Threshold

Pharmaceuticals, Inc., a number of companies with active clinical trials ongoing in NSCLC, including Abbott Laboratories, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, BioNumerik Pharmaceuticals, Inc., Celgene, GlaxoSmithKline, NovaRx Corporation, Onyx Pharmaceuticals, Inc., Pfizer Inc. and Regeneron Pharmaceuticals, Inc., and a number of companies with active clinical trials ongoing in advanced melanoma, including Amgen, Astellas Pharma, Eli Lilly, Onyx, Roche, Synta Pharmaceuticals Corp., and Vical Inc. among other companies.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the significant expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

There are many different approaches to using immunotherapies to treat cancer, including anti-idiotype, whole cell, DNA, peptide/antigen, viral, tumor lysate, shed antigens, and dendritic cell. Cancer immunotherapies are also distinguished by whether or not they are derived from autologous or allogeneic sources. Each of the various approaches to cancer immunotherapy have potential advantages and disadvantages based on factors such as their immunostimulatory mechanisms, formulation characteristics, manufacturing requirements, and treatment regimens.

We also compete with other clinical-stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors. Further, research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, D-1MT or our other potential products obsolete even before they begin to generate any revenue.

In addition, our competitors may obtain patent protection or FDA approval and commercialize products more rapidly than we do, which may impact future sales of any of our products that receive marketing approval. If the FDA approves the commercial sale of any of our products, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval, but cannot compete effectively in the marketplace.

If any of our product candidates are approved and commercialized, we may face competition from generic products if the product candidate is a small molecule drug, or biosimilars if the product candidate is a biologic. The route to market for generic versions of small molecule drugs was established with the passage of the Hatch-Waxman Amendments in 1984 and for biosimilars with the passage of the PPACA in March 2010. The PPACA establishes a pathway for the FDA approval of follow-on biologics and provides 12 years of marketing exclusivity for reference products and an additional six months of exclusivity if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

Our biodefense product candidates face significant competition for United States government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Competitors

include Emergent BioSolutions, SIGA Technologies, AVI Biopharma, Pharmathene, Acambis, Bavarian Nordic AS, and Novartis. Academic institutions, government agencies, private research organizations and public research organizations are also conducting research and filing patents toward commercialization of products. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Our products may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any.

Even if the HyperAcute product candidates, D-1MT or any of our other potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our products, if successfully developed, will compete with a number of traditional products and immunotherapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third party payors.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, to conduct our preclinical studies and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and cGCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with cGCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, we may be unable to commercialize them effectively or at all.

To successfully commercialize the HyperAcute product candidates or D-1MT, we will need substantial financial resources as well as expertise and physical resources and systems. We may elect to develop some or all of these physical resources and systems and expertise ourselves or we may seek to collaborate with

another company that can provide some or all of such physical resources and systems as well as financial resources and expertise. Such collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the HyperAcute product candidates and D-1MT, the costs and complexities of manufacturing and delivering the HyperAcute product candidates and D-1MT to patients, the potential of competing products, the existence of uncertainty with respect to ownership or the coverage of our technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. If we were to determine that a collaboration for the HyperAcute product candidates or D-1MT is necessary and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the HyperAcute product candidates or D-1MT in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

If we enter into a collaboration agreement we consider acceptable, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the HyperAcute product candidates or D-1MT;
- the collaborator may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of the HyperAcute product candidates or D-1MT reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the HyperAcute product candidates or D-1MT; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the HyperAcute product candidates or D-1MT.

If we enter into one or more collaborations for our HyperAcute product candidates, D-1MT or any of our other product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates that are difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the HyperAcute product candidates or D-1MT may have the right to terminate the collaboration at its discretion. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or require us to delay or scale back the commercialization efforts. The occurrence of any of these events could adversely affect the commercialization of the HyperAcute product candidates or D-1MT and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

We rely on a single manufacturer for a key component used in the manufacture of our HyperAcute immunotherapy product candidates, which could impair our ability to manufacture and supply our products.

The manufacturing process for our HyperAcute immunotherapy product candidates has one component that we obtain from a single manufacturer. If we utilize an alternative manufacturer, we may be

required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

We may explore strategic partnerships that may never materialize or may fail.

We may, in the future, periodically explore a variety of possible strategic partnerships in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic partnership might take. We are likely to face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

If we enter into one or more strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.

Any future strategic partnerships we enter into could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- strategic partners could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.

Our success will depend, in part, on our ability to obtain patents, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth, and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

There can be no assurance that we will discover or develop patentable products or processes or that patents will issue from any of the currently pending patent applications or that claims granted on issued patents will be sufficient to protect our technology or adequately cover the actual products we may actually sell. Potential competitors or other researchers in the field may have filed patent applications, been issued patents, published articles or otherwise created prior art that could restrict or block our efforts to obtain additional patents. There also can be no assurance that our issued patents or pending patent applications, if issued, will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted hereunder will provide us with proprietary protection or competitive advantages. Our patent rights also depend on our compliance with technology and patent licenses upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition, even where patent protection is obtained, third party competitors may challenge our patent claims in the various patent offices, for example via opposition in the European Patent Office or reexamination or interference proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions, and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents or pending applications. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents.

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities,

including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations.

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. Under the Abbreviated New Drug Application provisions of U.S. law, after four years from the date marketing approval is granted to us by the FDA for a patented drug, a generic drug company may submit an Abbreviated New Drug Application to the FDA to obtain approval to market in the United States a generic version of the drug patented by us. If approval were given to the generic drug company, we would be required to promptly initiate patent litigation to prevent the marketing of such generic version prior to the normal expiration of the patent. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any generic drug would be found to infringe our patents.

In addition, if our competitors file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial cost to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy, are costly to defend and involve complex questions of law and fact the outcomes of which are difficult to predict. An adverse outcome with respect to a third party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property become known to our competitors, it could result in a material adverse effect on our business, financial condition and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others in work for us, disputes may also arise as to the rights to related or resulting know-how and inventions.

Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at a reasonable rate in the future.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan, and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently carry clinical trial liability insurance in the amount of $5 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any products by us or our partners.

Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

We may become involved in securities class action litigation that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this "Risk Factor," section of this prospectus, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Offering Risks

We do not know whether a market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Before this offering, there was no public trading market for our common stock and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline, perhaps substantially, below the initial public offering price. The initial public offering price has been determined through negotiations between us and the representatives of the underwriters and may not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions; our results of operations and financial condition; financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us; the present state of our development; and our future prospects. See the "Underwriting" section of this prospectus for additional information. If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the NASDAQ Global Market or otherwise or how liquid that market might become. If a market for our common stock does not develop or is not sustained, it may be difficult for you

to sell your shares of common stock at an attractive price or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section in this prospectus and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic partners, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, including our Phase 3 clinical trial of our HyperAcute Pancreas product candidate, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts; actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst ratings downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has

often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of June 30, 2011, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 47.5% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after June 30, 2011, and we expect that upon completion of this offering, that same group will continue to hold at least % of our outstanding common stock. Accordingly, even after this offering, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares will may be distributed and subsequently voted.

A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the expiration of the lock-up agreements described in the "Underwriting" section of this prospectus. These sales, or the market perception that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have shares of common stock outstanding based on the number of shares outstanding as of June 30, 2011. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. The remaining shares, or % of our outstanding shares after this offering, are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future as set forth below.

Number of Shares and % of Total Outstanding	Date Available for Sale into Public Market
shares, or %	On the date of this prospectus
shares, or %	180 days after the date of this prospectus, subject to extension in specified instances, due to lock-up agreements between the holders of these shares and the underwriters. However, the representatives of the underwriters can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time.

In addition, as of June 30, 2011, there were 6,513,967 shares subject to outstanding options and an additional 1,535,986 shares reserved for future issuance under our employee benefit plans, of which 887,500 shares are issuable upon the exercise of options that have been approved by the Company's Board of Directors through July 29, 2011 and will be granted effective concurrently with the completion of this offering or as of December 31, 2011, if later, in each case that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, the lock-up agreements and

Rules 144 and 701 under the Securities Act of 1933, as amended, or the Securities Act. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If such holders, by exercising their registration rights, cause a large number of securities to be registered and sold into the public market, these sales could have an adverse effect on the market price for our common stock. We also intend to register all shares of common stock that we may issue under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed on our affiliates under Rule 144.

You will incur immediate and substantial dilution as a result of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share and our pro forma net tangible book value per share after giving effect to this offering and the conversion of all outstanding shares of our convertible preferred stock upon the closing of this offering. Moreover, we issued warrants and options in the past to acquire common stock at prices significantly below the assumed initial public offering price. As of June 30, 2011, there were 6,513,967 shares subject to outstanding options with a weighted average exercise price of $1.39 per share. To the extent that these outstanding options are ultimately exercised, you will incur further dilution.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to meet compliance obligations.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Stock Market, or NASDAQ, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required to publish a report by our management on our internal control over financial reporting. We have not been subject to these requirements in the past. The internal control report must contain (a) a statement of management's

responsibility for establishing and maintaining adequate internal control over financial reporting, (b) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (c) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (d) a statement that our independent registered public accounting firm has issued an attestation report on internal control over financial reporting.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan to (a) assess and document the adequacy of internal control over financial reporting, (b) take steps to improve control processes where appropriate, (c) validate through testing that controls are functioning as documented, and (d) implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions with respect to the effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

We do not expect to pay any cash dividends for the foreseeable future. Investors in this offering may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, our ability to pay cash dividends is currently prohibited by the terms of one of our debt financing arrangements, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

We expect to use the net proceeds from this offering primarily to fund the development activities for our HyperAcute immunotherapy product candidates. We also expect to use a portion of the proceeds to support the research and development of our other product candidates and the balance, if any, for working capital and other general corporate purposes, and any of the purposes described in the "Use of Proceeds" section of this prospectus. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Provisions in our certificate of incorporation, our by-laws or Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- limitation on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options and warrants or by future issuances of securities by us.

We may issue additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock. Furthermore, substantially all shares of common stock for which our outstanding stock options or warrants are exercisable are, once they have been purchased, eligible for immediate sale in the public market. The issuance of additional common stock, preferred stock, restricted stock units, or securities convertible into or exchangeable for our common stock or the exercise of stock options or warrants would dilute existing investors and could adversely affect the price of our securities. In addition, such securities may have rights senior to the rights of the securities purchased in this offering.

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code.

Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of our subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2009 and/or changes in our ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of this offering and other information that may not be available to us until after this offering has occurred. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

Accounting pronouncements may impact our reported results of operations and financial position.

United States generally accepted accounting principles, or GAAP, and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly alter our reported financial statements and results of operations.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our plans to develop and commercialize our product candidates;
- our ongoing and planned preclinical studies and clinical trials, including the timing for completion of enrollment and outcome of our Phase 3 clinical trial for HyperAcute Pancreas;
- the timing of release of data from ongoing clinical studies;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our products;
- our plans to leverage our existing technologies to discover and develop additional product candidates;
- our ability to quickly and efficiently identify and develop product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have

been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that our internal estimates and research and the industry publications, studies and surveys are reliable, this data involves a number of assumptions and you are cautioned not to give undue weight to such estimates, research, publications, studies and surveys.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of common stock in this offering will be approximately $ million (or approximately $ million if the underwriters' over-allotment option is exercised in full), assuming an initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this preliminary prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) our net proceeds from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this preliminary prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use approximately $ million of the net proceeds from this offering to fund to completion our Phase 3 clinical trial and related development activities for HyperAcute Pancreas, approximately $ million to fund clinical and related development activities for our other HyperAcute immunotherapy product candidates, approximately $ million to fund clinical and related development activities for our IDO pathway inhibitor product candidates and the remainder for working capital and other general corporate purposes. Our other HyperAcute immunotherapy product candidates have either started or completed Phase 1 clinical trials or completed the patient enrollment portion of Phase 2 clinical studies. Our IDO pathway inhibitor product candidates are in Phase 1 clinical trials and in multiple Phase 1/2 clinical trials. We intend to use the net proceeds from this offering to fund the completion of each of these ongoing studies. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will allow us to fund our operations through at least the end of 2012.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures depend on numerous factors, including the ongoing status and enrollment and site participation rates of, standard of care applicable to and results from clinical trials and other studies, as well as any strategic collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending use of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2011:

- on an actual basis;
- on a pro forma basis (i) to give effect to the issuance of 55,238 shares of Series E preferred stock in connection with our acquisition of the minority interest in our majority owned subsidiary, BPS, which were issued on August 12, 2011, after the closing of the acquisition, and (ii) the conversion of all of our outstanding convertible preferred stock into an aggregate of shares of common stock, which will take place automatically upon the closing of this offering in accordance with the terms of our preferred stock; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale.

The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a $1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

Our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus, the sections entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of June 30, 2011 (unaudited)		
	Actual	Pro Forma	Pro Forma As Adjusted (1)(2)
	(in thousands, except per share data)		
Cash, cash equivalents, and certificates of deposit	$ 9,800	$ 9,800	$
Redeemable preferred stock, $0.01 par value:			
Series AA preferred stock: 1,217,175 shares issued and outstanding actual; no shares issued or outstanding, pro forma or pro forma as adjusted	$ 2,191	$ —	$
Series AAA preferred stock: 377,410 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	849	—	
Series B preferred stock: 2,191,193 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	5,478	—	
Series BB preferred stock: 1,883,337 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	8,004	—	
Series C preferred stock: 6,000,000 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	30,000	—	
Series D preferred stock: 1,500,000 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	7,500	—	
Series E preferred stock: 680,998 shares issued and outstanding actual; no shares issued and outstanding, pro forma and pro forma as adjusted	21,250	—	
Equity:			
Series A preferred stock, $0.01 par value: 420,000 shares issued and outstanding, actual; no shares issued or outstanding, pro forma or pro forma as adjusted	1,030	—	
Common stock, $.01 par value: 7,662,222 shares issued and outstanding, actual; and 24,819,660 shares issued and outstanding, pro forma and shares issued and outstanding, pro forma as adjusted	77	248	
Additional paid-in capital	2,728	78,859	
Deficit accumulated during the development stage	(71,680)	(71,680)	
Total NewLink Genetics shareholders' (deficit) equity	(67,845)	7,427	
Total (deficit) equity	(67,845)	7,427	
Total capitalization	$ 7,427	$ 7,427	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of

this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(2) The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a $1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

The table above does not include:

- 1,164,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Equity Incentive Plan, or 2000 Plan, as of June 30, 2011 having a weighted average exercise price of $0.90 per share;
- 5,349,895 shares of common stock issuable upon the exercise of outstanding options under our 2009 Equity Incentive Plan, as amended, or 2009 Plan, as of December 31, 2010 having a weighted average exercise price of $1.50 per share, which includes 106,078 shares of common stock issuable upon the exercise of options that were issued in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS;
- 1,535,986 additional shares of common stock reserved for future issuance under our 2009 Plan, as amended and restated, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation—Employee Benefit Plans—2009 Equity Incentive Plan" section of this prospectus, of which 887,500 shares of common stock are issuable upon the exercise of options that have been approved by the Company's Board of Directors through July 29, 2011 and will be granted effective concurrently with the completion of this offering or as of December 31, 2011, if later; and
- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of June 30, 2011 was $(68.9) million or $(8.99) per share of our common stock. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities and convertible preferred stock, divided by the number of shares of common stock outstanding.

Our pro forma net tangible book value (deficit) as of June 30, 2011 was $6.4 million or $0.83 per share of our common stock. Pro forma net tangible book value (deficit) per share represents the amount of our total tangible assets less total liabilities and convertible preferred stock, divided by the total number of shares of common stock outstanding.

After giving effect to the issuance and sale by us of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, less underwriting discounts and commissions and estimated offering expenses payable by us, and the conversion of all outstanding shares of our convertible preferred stock into an aggregate of shares of common stock upon the closing of this offering. Our pro forma as adjusted net tangible book value as of June 30, 2011 would have been $ million, or $ per share. This represents an immediate increase in pro forma net tangible book value per share of $ to existing stockholders and immediate dilution of $ in pro forma net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share of common stock	$
Pro forma net tangible book value per share as of June 30, 2011	
Increase per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) our pro forma net tangible book value per share by approximately $, our pro forma as adjusted net tangible book value per share by approximately $ and dilution per share to new investors by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a

$1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

If the underwriters exercise their over-allotment option, the pro forma as adjusted net tangible book value will increase to $ per share, representing an immediate increase to existing stockholders of $ per share and an immediate dilution of $ per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

The following table summarizes, on the pro forma as adjusted basis described above as of June 30, 2011, the difference between the number of shares of common stock purchased from us, the total effective cash consideration paid to us and the average price per share paid to us by our existing stockholders and by investors purchasing shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors purchasing shares of our common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders		%	$	%	$
New investors					
Total		100%	$	100%	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the total consideration paid by new investors by $ million and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above.

The number of shares purchased from us by existing stockholders is based on 7,662,222 shares of common stock outstanding as of June 30, 2011, and excludes:

- 1,164,072 shares of common stock issuable upon the exercise of outstanding options under our 2000 Plan as of June 30, 2011 having a weighted average exercise price of $0.90 per share;
- 5,349,895 shares of common stock issuable upon the exercise of outstanding options under our 2009 Plan as of June 30, 2011 having a weighted average exercise price of $1.50 per share, which includes 106,078 shares of common stock issuable upon the exercise of options that were issued in connection with our acquisition of the minority interest in BPS in exchange for outstanding options to purchase the Series B common stock of BPS;
- 1,535,986 additional shares of common stock reserved for future issuance under our 2009 Plan as amended and restated, plus any annual increases in the number of shares of common stock reserved for future issuance under this plan pursuant to the "evergreen provision" in such plan, as more fully described in the "Executive Compensation—Employee Benefit Plans—2009 Equity Incentive Plan" section of this prospectus, of which 887,500 shares of common stock are issuable upon the exercise of options that have been approved by the Company's Board of Directors through July 29, 2011 and will be granted effective concurrently with the completion of this offering or as of December 31, 2011, if later; and

- 950,000 shares of common stock reserved for future issuance under our 2010 Non-Employee Directors' Stock Award Plan, or Directors' Plan, and 2010 Employee Stock Purchase Plan, or 2010 Purchase Plan, each of which will become effective upon the completion of this offering.

To the extent that outstanding options or warrants are exercised, you will experience further dilution. If all our outstanding stock options and outstanding warrants had been exercised as of June 30, 2011, assuming the treasury stock method, our pro forma net tangible book value as of June 30, 2011 would have been approximately $ million or $ per share of our common stock, and the pro forma net tangible book value after giving effect to this offering would have been $ per share, representing dilution in our pro forma net tangible book value per share to new investors of $.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

SELECTED FINANCIAL DATA

You should read the following selected consolidated financial data together with our financial statements, the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

We derived the annual consolidated financial data from our audited financial statements, the last three years of which are included elsewhere in this prospectus. Our unaudited interim consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the information set forth therein. We derived the summary statement of operations data for the years ended December 31, 2006 and 2007 and the balance sheet data as of December 31, 2006, 2007 and 2008 from our audited financial statements not included in this prospectus. We derived the interim consolidated financial data from our unaudited interim consolidated financial statements included elsewhere in this prospectus.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year.

	Years Ended December 31,					Six Months Ended June 30,	
	2006	2007	2008	2009	2010	2010	2011
	(in thousands, except per share data)					(unaudited)	(unaudited)
Statement of operations data:							
Grant revenue	$ 198	$ —	$ 633	$ 934	$ 2,079	$ 730	$ 1,141
Operating expenses:							
Research and development(1)	4,326	5,756	5,790	7,578	12,666	5,696	6,975
General and administrative(1)	1,897	2,364	3,938	3,705	6,074	2,284	2,452
Total operating expenses	6,223	8,120	9,728	11,283	18,740	7,980	9,427
Loss from operations	(6,025)	(8,120)	(9,095)	(10,349)	(16,661)	(7,250)	(8,286)
Other income and expense:							
Miscellaneous income	72	87	42	19	71	8	1
Forgiveness of debt	224	—	—	—	—		
Interest income	414	454	213	132	75	23	8
Interest expense	(3)	(1)	(2)	(9)	(47)	(19)	(15)
Other income, net	707	540	253	142	99	12	(6)
Net loss	(5,318)	(7,580)	(8,842)	(10,207)	(16,562)	(7,238)	(8,292)
Less net loss attributable to noncontolling interest(2)	—	—	—	233	349	151	1
Net loss attributable to NewLink	$ (5,318)	$ (7,580)	$ (8,842)	$ (9,974)	$ (16,213)	$ (7,087)	$ (8,291)
Net loss per share-basic and diluted	$ (0.83)	$ (1.17)	$ (1.35)	$ (1.50)	$ (2.30)	$ (1.06)	$ (1.08)
Weighted average shares outstanding—basic and diluted	6,369	6,460	6,542	6,636	7,040	6,710	7,647
Pro forma net loss per share—basic and diluted (unaudited)(3)					$		$
Weighted average pro forma shares outstanding (unaudited)(3)							

	As of December 31,					As of June 30,
	2006	2007	2008	2009	2010	2011
			(in thousands)			(unaudited)
Balance sheet data:						
Cash, cash equivalents, and certificates of deposit	$ 8,825	$ 16,238	$ 8,126	$ 17,209	$ 12,841	9,800
Working capital	5,421	(1,007)	7,186	15,657	11,377	3,255
Total assets	10,054	17,358	10,526	22,667	20,078	17,315
Notes payable and obligations under capital leases	5,001	6,000	6,008	6,113	7,294	7,260
Convertible preferred stock	17,664	17,664	35,583	55,164	62,775	76,302
Deficit accumulated during the development stage	(20,778)	(28,359)	(37,202)	(47,176)	(63,389)	(71,680)
Total deficit	$ (15,331)	$ (22,832)	$ (31,565)	$ (40,786)	$ (52,019)	(67,845)

(1) Research and development and general and administrative expenses were corrected for misclassification and immaterial errors in 2008, 2009 and 2010. See note 3 in the notes to the consolidated financial statements included in this prospectus.

(2) Further explanation is described under the caption "Noncontrolling Interest" in note 2(o) in the consolidated financial statements included in this prospectus.

(3) Pro forma as adjusted net loss per share and weighted average pro forma as adjusted shares outstanding assume the conversion of all our outstanding convertible preferred stock into an aggregate of shares of common stock as of January 1, 2010.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and the related notes to those statements included later in this prospectus. In addition to historical financial information, this discussion contains forward-looking statements reflecting our current plans, estimates, beliefs and expectations that involve risks and uncertainties. As a result of many important factors, particularly those set forth under the "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this prospectus, our actual results and the timing of events may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients. Our portfolio includes biologic and small-molecule immunotherapy product candidates to treat a wide range of oncology indications. Our lead product candidate, HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. We initiated this trial based on encouraging Phase 2 data that suggests improvement in both disease-free and overall survival. We have three additional product candidates in clinical development, including HyperAcute Lung, which is being studied in a Phase 1/2 clinical trial conducted at the National Cancer Institute, or NCI, and HyperAcute Melanoma, which is being studied in an investigator-initiated Phase 2 clinical trial. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients, either as a monotherapy or in combination with other therapies, and have demonstrated a favorable safety profile.

Our HyperAcute product candidates are based on our proprietary HyperAcute immunotherapy technology, which is designed to stimulate the human immune system. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens without incremental toxicity. We are also conducting small-molecule based research and development with an aim to produce new drugs capable of breaking the immune system's tolerance to cancer through inhibition of the indoleamine-(2,3)-dioxygenase, or IDO, pathway. We are currently studying our lead IDO pathway inhibitor product candidate, d-1-methyltryptophan, or D-1MT, in collaboration with the National Cancer Institute, or NCI, in multiple Phase 1B/2 clinical trials. We believe that our immunotherapeutic technologies will enable us to discover, develop and commercialize multiple product candidates that can be used either alone or in combination to enhance or potentially replace current therapies to treat cancer with underserved patient populations and significant market potential.

We are a development stage company and have incurred significant losses since our inception. As of June 30, 2011, we had an accumulated deficit of $71.7 million. We incurred a net loss of $8.3 million and $7.1 million for the six months ended June 30, 2011 and June 30, 2010, respectively, and $16.2 million, $10.0 million and $8.8 million for the years ended December 31, 2010, December 31, 2009, and December 31, 2008, respectively. We expect our losses to increase over the next several years as we advance into late-stage clinical trials and pursue regulatory approval of our product candidates. In addition, if one or more of our product candidates are approved for marketing, we will incur significant expenses for the initiation of commercialization activities.

Financial Overview

Revenues

From our inception through June 30, 2011, we have not generated any revenue from product sales. We have generated $5.0 million in grant revenue from our inception through June 30, 2011, which is primarily

attributable to research and development being performed by our subsidiary, BioProtection Systems Corporation, or BPS, under contracts and grants with the Department of Defense, or DOD, and the National Institutes of Health, or NIH.

In the future, we may generate revenue from a variety of sources, including product sales if we develop products which are approved for sale, license fees, and milestone, research and development and royalty payments in connection with strategic collaborations or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales for several years, if ever. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment;
- license fees for and milestone payments related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidates, and to further advance our earlier-stage research and development projects. From our inception through December 31, 2010, and June 30, 2011, we have incurred $46.1 million and $53.0 million, respectively, in research and development expenses. The following tables summarize our research and development expenses for the periods indicated:

Research and Development Expenses by Product
(in thousands)

	Years Ended December 31,			Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30, 2011
	2008	2009	2010	2010	2011	
HyperAcute immunotherapy technology	$ 3,247	$ 4,943	$ 8,760	3,911	4,815	$ 37,916
IDO pathway inhibitor technology	1,679	1,706	2,509	1,136	1,396	9,657
Other research and development	864	929	1,397	649	764	5,465
Total research and development expenses	$ 5,790	$ 7,578	$ 12,666	5,696	6,975	$ 53,038

Research and Development Expenses by Category
(in thousands)

	Years Ended December 31,			Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30, 2011
	2008	2009	2010	2010	2011	
Compensation	$ 2,573	$ 4,063	$ 5,965	2,947	3,305	$ 26,991
Equipment, supplies and occupancy	1,804	1,976	4,364	1,710	2,254	17,533
Outside clinical and other	1,413	1,539	2,337	1,039	1,416	8,514
Total research and development expenses	$ 5,790	$ 7,578	$ 12,666	5,696	6,975	$ 53,038

At this time, we cannot accurately estimate or know the nature, specific timing or costs necessary to complete clinical development activities for our product candidates. We are subject to the numerous risks and uncertainties associated with developing biopharmaceutical products including the uncertain cost and outcome of ongoing and planned clinical trials, the possibility that the FDA or another regulatory authority may require us to conduct clinical or non-clinical testing in addition to trials that we have planned, rapid and significant technological changes, frequent new product and service introductions and enhancements, evolving industry standards in the life sciences industry and our future need for additional capital. In addition, we currently have limited clinical data concerning the safety and efficacy of our product candidates. A change in the outcome of any of these variables with respect to the development of any of our product candidates could result in a significant change in the costs and timing of our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise associated with research and development expenses, intellectual property prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will continue to increase over the next several years for, among others, the following reasons:

- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, auditing and tax services and investor relations costs, and director and officer insurance premiums associated with being a public company;
- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue to advance the clinical development of our product candidates; and
- we may also begin to incur expenses related to the planned sales and marketing of our product candidates in anticipation of commercial launch before we receive regulatory approval, if any, of a product candidate.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents and certificates of deposit. The primary objective of our investment policy is capital preservation. We expect our interest income to increase as we invest the net proceeds from the offering pending their use in our operations.

Interest expense consists primarily of interest, amortization of debt discount and amortization of deferred financing costs associated with our loans payable.

Tax Loss Carryforwards

The valuation allowance for deferred tax assets as of June 30, 2011 and December 31, 2010, 2009 and 2008 was $16.4 million, $15.0 million, $11.6 million and $10.0 million, respectively. The net change in the total valuation allowance for the six-months ended June 30, 2011 and the years ended December 31, 2010, 2009 and 2008 was an increase of $1.4 million, $3.4 million, $1.6 million and $2.5 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of June 30, 2011 and December 31, 2010, 2009 and 2008, due to the uncertainty of future recoverability.

As of June 30, 2011 and December 31, 2010, we had federal net operating loss carryforwards of $66.5 million and $62.1 million and federal research credit carryforwards of $2.6 million and $2.1 million, respectively, that expire at various dates from 2020 through 2030. Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of our subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2009 and/or changes in our ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of this offering and other information that may not be available to us until after this offering has occurred. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of this offering, additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

We incurred no income tax expense for the six months ended June 30, 2011 or the years ended December 31, 2010, 2009 and 2008. Income tax expense differs from the amount that would be expected after applying the statutory United States federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with United States generally accepted accounting principles. Our preparation of these financial statements requires us to make estimates,

assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in note 2 to our financial statements included later in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued clinical expenses include:

- fees paid to contract research organizations in connection with clinical trials;
- fees paid to investigator sites in connection with clinical trials;
- fees paid to contract manufacturers in connection with the production of clinical trial materials; and
- fees paid to vendors in connection with preclinical development activities.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation

Stock Option Valuation. We are required to estimate the grant-date fair value of stock options issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each option granted using the Black-Scholes option pricing model. Generally, we have issued employee awards that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. We issue awards which typically vest 20% to 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, as determined by the Board of Directors at the time of grant.

We have issued awards to nonemployee consultants and advisers. All grants to nonemployees are valued using the same fair value method that we use for grants to employees. The compensation cost on these awards is recognized through the later of the vesting of the award or completion of services by the nonemployee.

The following table summarizes our assumptions used in the Black-Scholes model for option grants during the last three years and the six months ended June 30, 2011:

Black-Scholes Model Assumptions

	Years Ended December 31,			Six Months Ended June 30,
	2008	2009	2010	2011
Exercise price	$1.00	$1.00	$1.41-$3.41	$4.77
Expected volatility	54.5%-67.2%	69.4%	59.8%-68.1%	64.5%-67.7%
Expected term (in years)	5.5-7.5	7.5	5.0-7.5	5.4-7.5
Risk-free interest rate	1.5%-3.3%	1.6%	2.3%-3.5%	2.1%-3.8%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

Exercise Price. Our stock options are granted with an exercise price at or above the then current fair value of our common stock as determined by the Board of Directors. As an input to making this determination, the Board of Directors obtained a third-party valuation. See "Common Stock Fair Value" below.

Expected Volatility. Since prior to this offering we were a privately-held company, the estimated future expected volatility for each stock option valuation utilizes volatility rates of similar publicly traded companies considered to be in the same peer group. The volatility is calculated over a period of time commensurate with the expected term for the options granted.

Expected Term (in Years). The expected term of a stock option is the period of time for which the option is expected to be outstanding. We have a large number of options outstanding. There is no secondary market for our outstanding stock options and they contain only basic terms. Therefore, we used a simplified method of determining expected term by selecting the midpoint between the date upon which they would be fully vested in accordance with their terms and the anticipated forfeiture date as the expected term for the employee and non-employee director grants. For other non-employee grants, the contractual life of the option was used.

Risk-Free Interest Rate. We use the average yield on current United States Treasury instruments with terms that approximate the expected term of the stock options being valued.

Expected Dividend Yield. The expected dividend yield for all of our stock option grants is 0%, as we have not declared a cash dividend since inception, and do not expect to do so in the foreseeable future.

Forfeitures. The stock-based compensation expense recognized has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of our option plan, which we expect to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

Common Stock Fair Value. Due to the absence of an active market for our common stock, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined by our Board of Directors, with the assistance of our management, in good faith based on a number of objective and subjective factors including:

- the prices of our convertible preferred stock sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preference of our convertible preferred stock;
- our results of operations, financial position and the status of our research and development efforts;

- our stage of development and business strategy;
- the lack of liquidity of our private stock as a private company;
- valuations performed by an unrelated valuation specialist prepared in accordance with methodologies outlined in the AICPA Technical Practice Aid, "*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*";
- the likelihood of achieving a liquidity event for the shares of our common stock and underlying stock options, such as an initial public offering, given prevailing market conditions;
- the material risks related to our business; and
- the composition of and changes to our management team.

Common Stock Valuations. After taking into account management's recommendations based on the valuation reports prepared by the Mentor Group, Inc., a third-party valuation specialist, our Board of Directors adopted valuations of our common stock as of December 31, 2007, 2008 and 2009, March 31, 2010, June 30, 2010, September 30, 2010 and December 31, 2010. The valuations used the probability-weighted expected return method, or PWERM, to allocate our estimated enterprise value between our preferred stock and common stock. This method is generally considered appropriate to use when there are several distinct liquidity scenarios to be considered. Under the PWERM, we analyzed the value of our company using several scenarios, which included an initial public offering ("IPO Scenario"), sale of the Company ("Sale Scenario"), remaining a private enterprise ("Private Company Scenario") and a liquidation of the assets ("Liquidation Scenario").

In determining the value of the equity under each scenario, the traditional approaches to valuation were considered. We utilized the discounted cash flow method to provide a reliable means of representing the fair value of the equity through the potential operating results of the Company on a going concern basis. This method was utilized in the Private Company Scenario. We also considered the capital market approach. This approach was utilized because we were able to identify publicly traded guideline companies we considered sufficiently comparable to the Company. The capital market approach was used in the IPO Scenario. The asset accumulation approach was considered and utilized in the Liquidation Scenario. The business transaction approach was utilized because data was available on the sale of entire businesses that we considered to be comparable to the Company. We used this approach in the Sale Scenario.

We determined the value of our preferred stock and common stock under each scenario by allocating the equity value to each class of stock and discounting the value back to the present using a risk-adjusted discount rate. We then weighted the present value of the common stock under each scenario based upon the probability of each scenario occurring in order to determine a final indication of value for the common stock.

After calculating the estimated values of our preferred stock and common stock in each scenario, we then tested our expected pre-money enterprise values for our IPO and Sale Scenarios using the guideline public company, or GPC, method within the market approach. We believe this two-step approach is consistent with the guidance set forth by the American Institute of Certified Public Accountants in the AICPA Technical Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation," which we refer to as the AICPA Practice Aid.

As described in the AICPA Practice Aid, the market approach is one of three generally accepted valuation approaches. The market approach, and more specifically the GPC method within that approach, considers market transactions in businesses to develop measures that can be used in the valuation of the subject business. We believe that this method is useful if adequate information is available. Guideline public companies are publicly traded companies that provide a reasonable basis for comparison to the characteristics of the company being valued. Once these guideline companies have been identified, the GPC method then consists of developing ratios of value, or market multiples, based on the traded market value of each selected public company, as well as operating performance and financial condition indicators such as revenues, earnings and cash flow.

Valuation models require the input of highly subjective assumptions, and the valuation model we used is not the only valuation model available. Therefore, we cannot assure the accuracy of any particular valuation of our stock. Because our common stock has characteristics significantly different from that of publicly traded common stock and because changes in the subjective input assumptions can materially affect the fair value estimate, the models we used do not, in management's opinion, necessarily provide a reliable, single measure of the fair value of our common stock, and we will not use them to value our common stock once this offering is complete.

The Mentor Group, Inc. performed two distinct valuations for two different purposes for all valuations prior to the December 31, 2010 valuation. The valuation described below was performed for the purpose of calculating compensation expense for options grants pursuant to ASC 718 (formerly FAS 123R). A separate valuation was performed for purposes of determining the fair market value of our common stock for purposes of Section 409A of the Code, and was used to establish the exercise price of stock options. The valuations resulted in different fair values for accounting and tax purposes, reflecting differences in the applicable standards and guidance. The two values at December 31, 2010 were identical.

Liquidity Scenarios. For all of the valuations we considered a number of different liquidity scenarios, including an initial public offering of our common stock and an acquisition of our company. In all of these scenarios, the proceeds of the liquidation event were sufficient to provide a return to the holders of common stock. For each of the acquisition scenarios, we assumed different enterprise valuations and different dates and, consistent with the PWERM, in the acquisition scenarios we took into account the liquidation preferences that would be payable to the shares of our convertible preferred stock before any distribution of proceeds to holders of our common stock. We also considered that the holders of certain series of the convertible preferred stock would have the right to participate, after payment of the convertible preferred stock liquidation preference, in receiving their pro rata share of remaining proceeds payable to the common stock, up to a maximum amount per share of convertible preferred stock set forth in our certificate of incorporation. We also assigned a probability to an additional scenario in which we would be dissolved for no value and no proceeds would be available for any stockholder. In this scenario, we assumed that the common stock had a value of zero, since no proceeds would be available for distribution to the holders of common stock. The probability weightings assigned to these scenarios for our 2009 valuation were lower than those used in the prior retrospective valuations because, by that time, we had determined that an initial public offering or sale of the Company at a higher valuation was more likely.

IPO and Acquisition Scenarios in which Holders of Common Stock Will Realize a Return. For all of the valuations, we assigned probabilities to successful IPO Scenarios and to Sale Scenarios that would result in a return to the holders of our common stock. We considered that our success in completing either an initial public offering or sale that resulted in a return to the holders of our common stock would be dependent upon our realization of clinical milestones, together with our execution of our business plan and a receptive marketplace. For each of the valuations, the assumptions as to our enterprise value in the acquisition scenarios were the same as in the IPO Scenarios but, consistent with the PWERM, in the acquisition scenarios we took into account the liquidation preferences that would be payable to the shares of our convertible preferred stock before any distribution of proceeds to holders of our common stock. We also considered that the holders of the convertible preferred stock would have the right to participate, after payment of the convertible preferred stock liquidation preference, in receiving their pro rata share of remaining proceeds payable to the common stock, up to a maximum amount per share of convertible preferred stock set forth in our certificate of incorporation. As a result, the values per share of our common stock in the acquisition scenarios were less than the corresponding values per share of common stock in the IPO Scenarios.

Guideline Public Companies Analysis. We have completed an analysis using a set of guideline public companies. We noted that the assumed values for our company we used in our IPO Scenarios fell within the observed range of initial public offering values for the identified companies. We selected a subset of the

public companies we considered to be most similar to our company. We determined that each of the selected public companies was comparable to our company at the respective valuation dates because they are small capitalization companies engaged in either small molecule research or vaccines that are generally either in a pre-commercial stage or in the early stages of commercialization. As of each valuation date, we evaluated the market value of these companies' equity, excluding cash, and noted that these values were consistent with the enterprise values that we assumed as part of our IPO Scenarios and acquisition scenarios under the PWERM.

To analyze our valuation for each of our acquisition scenarios, we utilized the guideline transaction method. In this analysis, we reviewed approximately 20 companies in the biotechnology industry and compared the multiples from these transactions to the implied multiples for the acquisition scenarios. We calculated the median multiples of the transactions for enterprise value to sales, enterprise value to earnings before interest, taxes, depreciation and amortization and enterprise value to earnings before interest and taxes. We believe that the proprietary product mix and potential growth will increase the multiples from normalized multiples paid in the industry. However, we utilized multiples at or below the median multiples. Consequently, we have kept the market multiples within a reasonable range of the median market multiples for similar companies.

Discount Rate. Once we had allocated the per share values to our common stock and to each series of our convertible preferred stock at each of the future dates in our various scenarios, we calculated the present values of each per share amount to the valuation date, using a discount rates ranging from 46% to 67%. We believe that the discount rates selected are consistent with the required rates of return described in the AICPA Practice Aid for companies in a similar stage of development to us. Under the criteria set forth in the AICPA Practice Aid, for the valuations for the years ending December 31, 2007, 2008 and 2009, we determined that our company was no longer in the start-up stage but had generally not progressed beyond the first or early stage of development. Under the criteria set forth in the AICPA Practice Aid, for the periods ending March 31, 2010, June 30, 2010, and September 30, 2010, we determined that the Company was in the first or early stage of development from a technology-risk point of view and the bridge or initial public offering stage of development from a time-to-liquidity point of view.

Additionally, for the December 31, 2009 valuation, the discount rate we used to determine the value of the common stock was lower than in the prior retrospective valuations because we believed that our stage of development had progressed during 2009 under the framework described in the AICPA Practice Aid. For example, we made additional progress in our product development during 2009, including the receipt of interim data from our Phase 2 clinical trial of HyperAcute Pancreas. We closed our $7.5 million Series D preferred stock financing and had the final closing of our $30 million Series C preferred stock financing in July 2009 and September 2009, respectively.

Fair Value Estimates

After taking into account all of the assumptions and estimates described in our application of the PWERM and the GPC method within the market approach, we determined the fair value of our common stock to be approximately $0.96 per share as of December 31, 2007, approximately $0.95 per share as of December 31, 2008, approximately $2.02 per share as of December 31, 2009, approximately $2.08 per share as of March 31, 2010, approximately $2.25 per share as of June 30, 2010, approximately $4.02 per share as of September 30, 2010 and approximately $4.77 per share as of December 31, 2010. The following table

lists grants of options to purchase shares of common stock with GAAP measurement dates in 2009, 2010 and 2011.

Options Granted on Shares of Common Stock

Approval Date(1)	GAAP Measurement Date(2)	Number of shares	Exercise price per share	Common Stock values	Intrinsic value per share
July 16, 2008	September 2, 2009	364,000	1.00	1.05	0.05
August 6, 2008	September 2, 2009	490,000	1.00	1.05	0.05
May 13, 2009	September 2, 2009	2,267,000	1.00	1.05	0.05
December 4, 2009(3)	March 3, 2010	1,706,500	1.41	2.08	0.67
March 3, 2010	June 2, 2010	1,005,250	1.46	2.25	0.79
June 2, 2010	October 8, 2010	13,000	1.91	4.02	2.11
October 8, 2010(4)	January 19, 2011	26,500	3.41	4.77	1.36
December 9, 2010(5)	April 14, 2011	160,000	4.77	4.77	0
January 19, 2011	January 19, 2011	71,000	4.77	4.77	0
April 14, 2011	April 14, 2011	45,000	4.77	4.77	0
April 14, 2011(6)	—	854,000	—	—	—
July 29, 2011(7)	—	33,500	—	—	—

(1) The Approval Date is the date on which the Board of Directors authorized, and we had a legal obligation to issue, an option grant.

(2) The GAAP Measurement Date is the first date at which the number of shares and exercise price per share were known and the awards were communicated to all recipients. The GAAP Measurement Date occurs subsequent to the Approval Date due to the timing of the completion and approval of third-party valuation reports of our common stock. We utilize the common stock value from the most recent valuation report that has been completed and approved at the time of the GAAP Measurement Date. Due to the significance of the number of option grants on September 2, 2009, management also obtained a third-party valuation on that date.

(3) The options granted on December 4, 2009 are not reflected in the disclosure in note 13 of the financial statements for the period ended December 31, 2009 as the measurement date had not yet occurred under GAAP. The GAAP Measurement Date did not occur until March 3, 2010, which was the date the exercise price per share was determined for accounting purposes based on completion and approval of the December 31, 2009 common stock valuation report and the awards were communicated to all recipients.

(4) The options granted on October 8, 2010 are not reflected in the disclosure in note 13 of the financial statements for the period ended December 31, 2010 as the measurement date had not yet occurred under GAAP. The GAAP Measurement Date did not occur until January 19, 2011, which was the date the exercise price per share was determined for accounting purposes based on completion and approval of the September 30, 2010 common stock valuation report and the awards were communicated to all recipients. These option grants are expected to result in the recognition of approximately $16,000 in share-based compensation expense during the year ended December 31, 2011.

(5) The options granted on December 9, 2010, are not reflected in the disclosure in note 13 of the financial statements for the period ended December 31, 2010 as the measurement date had not yet occurred under GAAP. The GAAP Measurement Date did not occur until April 14, 2011, which was the date the exercise price per share based on completion and approval of the December 31, 2010 common stock valuation report and the awards were communicated to all recipients. We do not believe the fair value of our common stock on April 14, 2011 was materially different than the value at

December 31, 2010; therefore the December 31, 2010 value was used to measure the stock option award. These options grants are expected to result in the recognition of approximately $210,000 in share-based compensation expense during the year ended December 31, 2011.

(6) Certain options approved on April 14, 2011 are not reflected in the disclosure in note 13 of the financial statements for the period ended June 30, 2011 as the measurement date had not yet occurred under GAAP. The GAAP Measurement Date will not occur until the earlier of the completion of the Company's initial public offering or December 31, 2011.

(7) Subsequent to June 30, 2011, certain options were approved on July 29, 2011 and are not reflected in the disclosure in note 13 of the financial statements for the period ended June 30, 2011.

The following table summarizes the significant assumptions used by our valuation consultant in the PWERM pricing model used to determine the fair value of our common stock as of the date indicated.

	12/31/2008	12/31/2009	3/31/2010	6/30/2010	9/30/2010	12/31/2010
PWERM weightings						
Private company	20.0%	20.0%	20.0%	20.0%	25.0%	30.0%
Merger or acquisition	30.0%	30.0%	30.0%	30.0%	25.0%	15.0%
Initial Public Offering	5.0%	30.0%	30.0%	30.0%	40.0%	45.0%
Liquidation	45.0%	20.0%	20.0%	20.0%	10.0%	10.0%
Value by method						
Private company scenario	0.71	1.66	1.78	2.10	4.22	4.67
Merger or acquisition	2.25	2.95	2.92	3.09	4.68	5.81
Initial Public Offering	2.65	2.67	2.82	2.99	4.48	5.55
Liquidation	—	—	—	—	—	—
Weighted value						
Private company scenario	0.14	0.33	0.36	0.42	1.06	1.40
Merger or acquisition	0.68	0.89	0.88	0.93	1.17	0.87
Initial Public Offering	0.13	0.80	0.85	0.90	1.79	2.50
Liquidation	—	—	—	—	—	—
	0.95	2.02	2.08	2.25	4.02	4.77
Lack of marketability discount	45%	30%	30%	15%	15%	0%

The estimated per share fair value of our common stock increased from January 1, 2009 to December 31, 2009 from $0.95 to $2.02. This increase in estimated fair value primarily reflected operational factors, including advancement of Hyperacute Lung, Hyperacute Pancreas and Hyperacute Melanoma Phase 2 clinical trials and concurrent increases in our enrollment for these trials from 20 patients in 2008 to 71 patients in 2009. We also initiated the treatment phase of our Phase 1 clinical trial in D-1MT. Data on D-1MT was presented at the annual meeting of the American Society of Clinical Oncologists, or ASCO, during this period. The increase is also due to our improving financial strength. During this period, BPS signed a $3.7 million contract with the federal government to study HyperAcute technology in the infectious disease setting. We also raised an additional $12 million in our existing Series C preferred stock financing and $7.5 million in a new Series D preferred stock financing. External factors that increased the estimated fair value included Dendreon Corporation's announcement that its Provenge immunotherapy product candidate demonstrated a survival benefit in its Phase 3 clinical trial.

The estimated per share fair value of our common stock increased from January 1, 2010 to March 31, 2010 from $2.02 to $2.08. This increase primarily reflected continued progress in our ongoing clinical trials, including the receipt of the FDA's letter of concurrence related to our Special Protocol Assessment request for our HyperAcute Pancreas Phase 3 clinical trial.

The estimated per share fair value of our common stock increased from April 1, 2010 to June 30, 2010 from $2.08 to $2.25 per share. This increase primarily reflected the encouraging data received from our ongoing HyperAcute Pancreas and HyperAcute Melanoma Phase 2 clinical trials and acceptance for presentation at the ASCO annual meeting in June 2010. We also treated our first patient in our HyperAcute Pancreas Phase 3 clinical trial during this period. In addition, prior to 2010, we had manufactured all of our HyperAcute cancer immunotherapy product candidates in a small good manufacturing practice, or GMP, laboratory setting and in April 2010, we began to occupy our first commercial scale GMP manufacturing facility. External factors that affected estimated fair value during this period included the FDA's May 2010 approval of Dendreon Corporation's Provenge.

The estimated per share fair value of our common stock increased from July 1, 2010 to September 30, 2010 from $2.25 to $4.02 per share. This increase was primarily due to our initiating the process associated with this offering with an organizational meeting on September 8, 2010. Additionally, in July 2010, we negotiated acceleration of the development milestones associated with our prior acquisition of OncoRx Corporation.

The estimated per share fair value of our common stock increased from October 1, 2010 to December 31, 2010 from $4.02 to $4.77 per share. This increase is due to many factors. As of December 31, 2010, we had nearly completed follow-up data on the HyperAcute Pancreas Phase 2 clinical trial, which was used to support our ongoing HyperAcute Pancreas Phase 3 clinical trial. In December 2010, we negotiated the acquisition of the noncontrolling interest in BPS. In October 2010, we received both Orphan Drug and Fast Track designations from the FDA for HyperAcute Pancreas. In December 2010, we raised $7.7 million in a new Series E preferred stock financing and completed the initial filing of our Registration Statement on Form S-1 associated with this offering. As of December 31, 2010, we had enrolled 60 patients and initiated 30 sites in our ongoing HyperAcute Pancreas Phase 3 clinical trial.

Based on an assumed initial public offering price of $ per share, which is the midpoint of the range set forth on the cover page of this prospectus, the intrinsic value of stock options outstanding at December 31, 2010, would have been $ million, of which $ million and $ million related to stock options that were vested and unvested, respectively, at that date.

Results of Operations

Six Months Ended June 30, 2011 and 2010

Revenues. Revenues for the six months ended June 30, 2011 were $1.1 million, increasing from $730,000 for the same period in 2010. The increase in revenue of $370,000 was due to increased progress on research by BPS under various DOD contracts and NIH grants.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2011 were $7.0 million, increasing from $5.7 million for the same period in 2010. The $1.3 million increase was primarily due to a $540,000 increase in equipment and supplies costs including direct development expenses for our clinical trial activities and other expenses, accompanied by a $360,000 increase in personnel-related expenses and a $380,000 increase in depreciation and amortization expense.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2011 were $2.5 million, increasing from $2.3 million for the same period in 2010. The $168,000 increase was primarily due to a $152,000 increase in personnel expenses, a $16,000 increase in occupancy-related and other costs.

Interest Income and Expense. Interest expense for the six months ended June 30, 2011 was $15,000, compared to $19,000 for the same period in 2010. Interest income for the six months ended June 30, 2011 was $8,000, compared to $23,000 for the same period in 2010. The $15,000 decrease was due to a decrease in interest rates partially offset by an increase in our average cash balances.

Other Income (Expense). Miscellaneous income, net for the six months ended June 30, 2011 was $1,000, compared to $8,000 for the same period in 2010.

Years Ended December 31, 2010, 2009 and 2008

Certain immaterial corrections were recorded, which impacted the results for the years ended December 31, 2010, 2009, and 2008. See note 3.

Revenues. Revenues for the year ended December 31, 2010 were $2.1 million, increasing from $934,000 for the same period in 2009. The increase in revenue of $1.1 million was due to an increase in billings of $860,000 by BPS under various DOD contracts and NIH grants and the receipt of $240,000 in section 48D income tax credits by NewLink.

Revenues for the year ended December 31, 2009 were $934,000, increasing from $633,000 for the same period in 2008. The increase in revenue of $301,000 was primarily due to increased billings by BPS under various DOD contracts and NIH grants.

The DOD contracts and NIH grants provide us with cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. Revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the cost reimbursement was provided have been met and we have only perfunctory obligations outstanding. As of December 31, 2010, $3.3 million in funding remained under the terms of these agreements.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2010 were $12.7 million, increasing from $7.6 million for the same period in 2009. The $5.1 million increase was due to a $2.4 million increase in equipment, supplies and occupancy costs including the acquisition of in-process research and development, accompanied by a $1.9 million increase in personnel-related expenses and a $800,000 increase in outside clinical and other expenses including direct development expenses for our clinical trial activities.

Research and development expenses for the year ended December 31, 2009 were $7.6 million, increasing from $5.8 million for the same period in 2008. The $1.8 million increase was primarily due to a $1.5 million increase in personnel-related expenses, accompanied by a $172,000 increase in equipment, supplies, and occupancy costs, and a $126,000 increase in outside clinical and other costs.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2010 were $6.1 million, increasing from $3.7 million for the same period in 2009. The $2.4 million increase was primarily due to a $1.0 million increase in professional fees, a $864,000 increase in personnel-related expenses, a $129,000 increase in equipment, supplies and occupancy costs, and a $374,000 increase in other costs.

General and administrative expenses for the year ended December 31, 2009 were $3.7 million, decreasing from $3.9 million for the same period in 2008. The $233,000 decrease was primarily due to a $151,000 decrease in other expenses accompanied by an $86,000 decrease in personnel-related expenses offset by a $4,000 increase in equipment, supplies and occupancy costs.

Interest Income and Expense. Interest expense for the year ended December 31, 2010 was $47,000, compared to $9,000 for the same period in 2009. The $38,000 increase was due to increased borrowings under notes payable and capital lease obligations. Interest income for the year ended December 31, 2010 was $75,000, compared to $132,000 for the same period in 2009. The $57,000 decrease was primarily due to a decrease in interest rates, partially offset by an increase in our average cash balances.

Interest expense for the year ended December 31, 2009 was $9,000, compared to $2,000 for the same period in 2008. Interest income for the year ended December 31, 2009 was $132,000, compared to $213,000 for the same period in 2008. The $81,000 decrease was primarily due to a decrease in interest rates.

Other Income (Expense). Miscellaneous income, net for the year ended December 31, 2010 was $71,000, compared to $19,000 for the same period in 2009. Miscellaneous income, net for the year ended December 31, 2009 was $19,000, compared to $42,000 for the same period in 2008.

Liquidity and Capital Resources

We have funded our operations principally through the private placement of equity securities, debt financing and interest income. As of June 30, 2011, we have received proceeds, net of offering costs, of $76.3 million from the issuance of convertible preferred stock, including $7.5 million from the sale of 1.5 million shares of Series D preferred stock in July 2009, $30.0 million from the sale of 6.0 million shares of Series C preferred stock in during the course of 2008 and 2009, and $21.4 million from the sale of 684,624 shares of Series E preferred stock during the course of 2010 and the first half of 2011 of which $8.6 million was issued to acquire the minority interest in BPS. As of June 30, 2011, we had cash, cash equivalents and certificates of deposit of approximately $9.8 million. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

Sources and Uses of Cash
(in thousands)

	Years Ended December 31,			Six Months Ended June 30,	
	2008	2009	2010	2010	2011
Net cash used in development activities	$ (8,885)	$ (9,140)	$ (13,270)	$ (5,560)	$ (7,891)
Net cash used in investing activities	(3,127)	(1,545)	(2,709)	(2,515)	1,965
Net cash provided by financing activities	17,930	19,626	11,334	1,430	4,904
Net increase (decrease) in cash and cash equivalents	$ 5,918	$ 8,941	$ (4,645)	$ (6,645)	$ (1,022)

For the six months ended June 30, 2011 and 2010, we used cash of $7.9 million and $5.6 million for our development activities, respectively. During 2010, 2009 and 2008, our development activities used cash of $13.3 million, $9.1 million and $8.9 million, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. The increase in cash used for the year ended 2010 resulted from an increase in research and development activities and general and administrative expenses. The increase in cash used for the year ended 2009 resulted from an increase in research and development activities offset by a decrease in general and administrative expenses.

For the six months ended June 30, 2011 and 2010, our investing activities provided (used) cash of $2.0 million and $(2.5) million, respectively. The cash provided by investing activities in the six months ended June 30, 2011 was primarily due to the sale of investments for net proceeds of $2.0 million. The cash used by investing activities in the six months ended June 30, 2010 was primarily a result of the purchases of property and equipment of $2.8 million related to the expansion of our manufacturing facilities at our corporate headquarters, as well as the purchase of $250,000 of investments offset by the repayment of $500,000 of notes receivable from related parties. During 2010, 2009 and 2008, our investing activities used cash of $(2.7) million, $(1.5) million and $(3.1) million, respectively. The use of cash for the year ended December 31, 2010 was primarily the result of the purchases of property and equipment of $2.9 million related to the expansion of our manufacturing facilities at our corporate headquarters. The use of cash for the years ended 2009 and 2008 was primarily the net result of the purchase of investments accompanied by the purchases of property and equipment of $1.4 million and $427,000, respectively.

For the six months ended June 30, 2011 and 2010, our financing activities provided $4.9 million and $1.4 million, respectively. The cash provided by financing activities in the six months ended June 30, 2011 was primarily due to the sale and issuance of Series E Preferred stock for net proceeds of $5.0 offset by

payments on long-term financing obligations of $100,000. The cash provided by financing activities in the six months ended June 30, 2010 was primarily due to $1.1 million in proceeds from notes payable and $300,000 cash received from noncontrolling interest investment. During 2010, 2009 and 2008, our financing activities provided $11.3 million, $19.6 million and $17.9 million, respectively. The cash provided by financing activities in the year ended December 31, 2010 was primarily due to the sale and issuance of Series E preferred stock for net proceeds of $7.8 million along with the exercise of a warrant for net proceeds of $2.0 million, proceeds from loans payable of $1.1 million and cash received from noncontrolling interest investment of $911,000. The cash provided in 2009 was primarily a result of the continued sale and issuance of Series C preferred stock along with 1.5 million shares of Series D preferred stock for net proceeds of $19.6 million. The cash provided by financing activities in 2008 was primarily due to the sale and issuance of Series C preferred stock for net proceeds of $17.9 million.

Series E Preferred Stock

On December 13, 2010 we completed the sale of 248,320 shares of our Series E preferred stock at a price per share of $31.25, which resulted in aggregate proceeds of $7.8 million. On June 20, 2011, we issued and sold to an investor an additional 160,000 shares of Series E preferred stock at a purchase price of $31.25 per share, which resulted in gross proceeds of $5.0 million. The Series E preferred stock is convertible into common stock at a 15% discount to the price to the public in an initial public offering if the offering results in at least $20 million in gross proceeds to us and occurs prior to December 31, 2011, or $6.25 per common share under any other conversion scenario.

On January 7, 2011, we acquired the minority interest in BPS. We issued 276,304 shares of our Series E preferred stock as consideration for this acquisition of which 221,066 shares were issued on January 7, 2011 and 55,238 shares were issued on August 12, 2011.

Loan Agreements

March 2005 Iowa Department of Economic Development Loan

In March 2005, we entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development, or the IDED. Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDED. The project is to provide assistance to the Company for research and product development activities at its Iowa State University Research Park facility. The project calls for the creation of 315 positions and retention of 35 positions with total project expenditures of $189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs. As of June 30, 2011, we believe we have created 43 jobs, retained 35 jobs and incurred approximately $70.5 million of project expenditures.

If, as of March 18, 2012, which is the current project completion date under the agreement, the IDED determines we have fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date we will be required to repay the greater of approximately $17,000 for each of the 350 jobs we fail to create and maintain as of that date or a percentage of the $6 million advanced under the agreement equal to the percentage of any shortfall in our obligation to expend $189.9 million of project expenditures. As of June 30, 2011, we had $4.7 million in outstanding debt subject to repayment. Five years following the project completion date, we will be required to repay approximately $17,000 for each of the 350 jobs the IDED determines we fail to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6% interest per annum beginning at the date of default.

Under the agreement, we are obligated to pay a minimum of 0.25% royalties on all gross revenues of our products with a cumulative maximum royalty amount due of $3.2 million. Royalties we pay will first

offset amounts we are required to repay for amounts of the loan not forgiven and then go toward reducing the total cumulative royalty to be paid. We are also obligated to maintain our business in the State of Iowa while amounts remain outstanding under the loan. Substantially all of our assets are pledged against this loan and we are required to submit audited financial statements within 90 days of year-end. We have failed to meet this covenant each year and have obtained a waiver from the IDED each year.

The original project completion date for the project was March 18, 2010 and was initially extended to March 18, 2011 by amendment to the agreement approved by the IDED. Based on our progress on the project we requested and received a second extension of the project completion date to March 18, 2012.

September 2007 IDED High Quality Job Creation Program Tax Credit

In September 2007, we entered into a master contract and associated funding agreement, or HQJC Agreement, with the IDED under its high quality job creation program. We amended the HQJC Agreement in 2010 to extend the dates by which certain job creation and investment requirements were to be met to March 18, 2011.

The terms of the HQJC Agreement, as amended, require us by March 18, 2012, to make a qualifying investment in real estate or depreciable assets of at least $2.0 million, to finalize the lease of our new executive offices and manufacturing facilities and to create at least 45 new full time equivalent jobs in Iowa of which at least 14 must be high quality, or HQJC jobs. In order to qualify as high quality jobs, the jobs created must be at a compensation levels that exceed the county average hourly wage of $17.31. We fulfilled two of the three requirements by March 18, 2010. We have made a qualified investment in real estate and finalized the lease of our new offices and manufacturing facility. As of June 30, 2011, we have created 44 new jobs of which 27 were HQJC jobs. In addition, we are required to retain the HQJC jobs through March 18, 2013. If we fail to meet this requirement we will be required to repay all tax credits received under the HQJC Agreement. As of June 30, 2011, we had maintained our base employment of 34 full time equivalent jobs in addition to the 44 newly created jobs.

Under the HQJC Agreement, we received a tax credit of $414,000, which was refunded to us between March 2006 and October 2009. Under the HQJC Agreement, the IDED may require us to repay the entire amount of the tax credit upon certain events of default, which include our experiencing a substantial layoff, relocating a substantial portion of our business or our research and development outside of Iowa, failing to offer certain employee benefits or failing to reinvest at least 1.0% of our pre-tax profits from our Iowa facility in research and development in Iowa. In addition, prior notice and consent of the IDED is required during the term of the HQJC Agreement for any material changes in our business or our research and development activities.

March 2010 City of Ames Forgivable Loan

In March 2010, we entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides us with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015.

The project calls for our creating or retaining at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and the creating or maintaining at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for our entering into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, we have failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, we will be required to repay approximately $3,100 per job not created or retained following the respective date. As of June 30, 2011, we had created or retained an aggregate of 76 full-time jobs in Ames, Iowa. As of June 30, 2011,

$300,000 of the total $400,000 forgivable loan was advanced to us with the final $100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses related to the research and development of our HyperAcute immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and certificates of deposit, will allow us to fund our operations through at least the end of 2012.

We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biopharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at June 30, 2011:

Contractual Obligations Due
(in thousands)

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Short and long-term debt (including interest)	$ 7,071	$ 6,113	$ 225	$ 501	$ 232
Operating lease obligations	1,046	303	540	203	—
Capital lease obligations	303	74	189	36	4
Total contractual cash obligations	$ 8,420	$ 6,490	$ 954	$ 740	$ 236

Under the license agreements described below in "Financial Obligations Related to Licensing and Development—In-Licensing Agreements," we are obligated to make potential milestone payments as listed in the following table. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined.

Licensor	Aggregate potential milestone payments
Drexel University	$1 million per licensed product
Lankenau Institute for Medical Research under the IDO-1 Agreement(1)	$1.36 million per licensed product
Lankenau Institute for Medical Research under the LIMR IDO-2 Agreement(1)	$1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement
Lankenau Institute for Medical Research under the 2009 LIMR Agreement(1)	$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement
Medical College of Georgia	$2.8 million per licensed product
University of British Columbia	$1.8 million per licensed product
Regents of the University of California	$285,000 per licensed product
Her Majesty the Queen in Right of Canada	C$205,000 per licensed product

(1) As defined below in the "Financial Obligations Related to Licensing and Development—In-Licensing Agreements" section of this prospectus.

To date, we have made payments in an aggregate amount of approximately $2.86 million under all of the in-licensing agreements listed in the "Financial Obligations Related to Licensing and Development—In-licensing Agreements" section of this prospectus.

Financial Obligations Related to Licensing and Development

In-Licensing Agreements

We are subject to a number of licensing agreements with respect to certain of the technologies that underlie our intellectual property. Unless otherwise noted, these agreements typically provide that we have exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to us meeting our financial and other contractual obligations under the agreements. Certain of the key licensing agreements with significant financial obligations include the following:

Central Iowa Health Systems. We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to our HyperAcute immunotherapy technology. In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares.

In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we commercialize a licensed product, we also have the obligation to pay CIHS royalties as

a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a sublicense under the licenses granted by CIHS, we must pay to CIHS a percentage of certain consideration paid by the sublicensee to us. Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets.

Drexel University. We are party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants us, and our affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on a-Gal epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease.

In consideration of our license under the Drexel Agreement, we have paid and are obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately $1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if we grant a sublicense under the license granted by Drexel, we must pay Drexel a percentage of the consideration paid by the sublicensee to us. In accordance with a development plan included in the Drexel Agreement, we are obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable.

Lankenau Institute for Medical Research—IDO-1. We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, and sell products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics.

In consideration of the license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee. Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

Medical College of Georgia. We are a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI, which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, we are obligated to pay to MCGRI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by MCGRI, we must pay to MCGRI a percentage of the consideration we receive from the sublicensee. Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods.

University of British Columbia. We are a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants us an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants us an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.

In consideration of the license grant, we must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.8 million per licensed product, and royalties in a range of 10% or less of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if we grant a sublicense under the licenses granted by UBC, we may be required to pay to UBC a percentage of certain consideration we receive from the sublicensee. We are obligated to use our commercially reasonable efforts to develop and market the licensed products, and to achieve certain specific development milestones by agreed-upon deadlines.

LIMR—IDO-2. We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target indoleamine 2,3 dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of the license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately $1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license.

2009 LIMR Exclusive License Agreement. We are a party to a license agreement, or the 2009 LIMR Agreement, dated April 23, 2009 with LIMR. The 2009 LIMR Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately $610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Bresagen Patent License Agreement. We are a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants us a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines in the U.S. In consideration of such license grant, we are obligated to pay Bresagen an up front license fee and an annual license fee.

Regents of the University of California License Agreement. BPS is a party to a license agreement dated July 29, 2008, or the California License, with the Regents of the University of California, or California. The California License grants BPS an exclusive, worldwide license, under specified California patent rights relating to technology based on yellow fever virus, to make, use, import, sell and offer for sale products that are covered by licensed patent rights in the field of human healthcare.

In consideration of the license grant, BPS must pay to California a specified license issue fee, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $285,000 per licensed product, and royalties as a low single-digit percentage of net sales of the licensed product, which royalty rate varies depending on the territory. In addition, if BPS grants a sublicense under the licenses granted by California, BPS may be required to pay to California a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

Her Majesty the Queen in Right of Canada License Agreement. BPS is a party to a license agreement dated May 4, 2010, or the Canada License, with the Her Majesty the Queen in Right of Canada, or Canada. The Canada License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified Canada patent rights relating to technology based on rVSV.

In consideration of the license grant, BPS must pay to Canada a specified patent and signing fees, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$205,000 per licensed product, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, which royalty rate varies depending on the type of licensed product. In addition, if BPS grants a sublicense under the licenses granted by Canada, BPS is required to pay to Canada a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products.

Collaborative Agreements with Medical Institutions

We have entered into numerous agreements with various medical institutions for the performance of clinical trials for various products. They typically call for the payment of fees by us for the performance of the clinical trials and the maintenance of confidentiality as to the associated technology.

We have entered into a letter of intent, or LOI, dated May 7, 2007 for a Cooperative Research & Development Agreement, or CRADA, with the NCI regarding certain IDO development efforts, which have consisted to date of primarily preclinical and Phase 1 clinical development of D-1MT. The LOI permits us to conduct informal joint research with the NCI pending formal approval of the CRADA. In the absence of an approved CRADA, we do not have any rights to inventions or raw data generated by NCI. We do have the right to use any clinical data generated under the LOI for exclusive use in obtaining regulatory approval.

If the CRADA is approved, it will have retroactive effect to the date that the last party executed the LOI, which is May 23, 2007, for any inventions that may be made pursuant to the joint research under the LOI. The financial obligations under the LOI will be defined in the CRADA when and if one is executed relating to this program. The term of the LOI has been extended until May 23, 2012. The CRADA is currently under active negotiation and the informal joint research is continuing. If the NCI discontinued support under the LOI, we would take over completing the development of D-1MT without federal support.

Patents and Trademarks

As noted above, we presently have an extensive portfolio of patents and patent applications (and certain trademark registrations) with the United States Patent and Trademark Office. During the six-months ended June 30, 2011 and June 30, 2010, we incurred expenses related to the filing, maintenance, and initiation of our patent portfolio of $185,000 and $332,000, respectively, for a decrease of 44% for the 2011 period as compared to the same period in 2010. During the fiscal years ending December 31, 2010, 2009 and 2008, these expenses totaled $722,000, $424,000 and $457,000. These expenses increased by $298,000 or 70% for 2010 compared to 2009. We anticipate these expenses will continue to increase into 2012.

OncoRx Acquisition

On June 21, 2005, we acquired all of the stock of OncoRx Corporation for $120,000 in cash and an agreement to deliver 780,611 shares of the our common stock, due in four installments upon successful completion of specified milestones as set forth in the agreement. On July 29, 2010, we entered into an amendment of this stock purchase agreement to reduce the remaining shares payable under the third and fourth installments by accelerating the payment of such installments to the effective date of the amendment. In consideration for our accelerated stock payment, we received a 30% discount on the remaining shares payable, reducing our total shares payable under the agreement by 156,122 shares. Through this acquisition, we acquired the fundamental technology for our IDO pathway inhibitor product candidates, subject to the licensing agreement with LIMR as set forth in "In-Licensing Agreements," above.

BioProtection Systems Corporation

We formed BioProtection Systems Corporation, or BPS, as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid response prophylactic and therapeutic treatment for pathogens that might be targeted to the human population through acts of bioterrorism. At December 31, 2010, we owned shares of BPS Series A common stock representing approximately 64% of BPS's common stock on an as-converted basis, assuming conversion into BPS Series B common stock of all outstanding BPS Series A and BPS Series B preferred stock. On December 1, 2010, we entered into an agreement to acquire all of the noncontrolling interest in BPS, as described in more detail below.

BPS has financed its operations since inception through a combination of stock sales to and loans from the Company, sales of preferred stock to investors, and government contracts. We hold 7,000,000 shares of Series A common stock in BPS. These shares have a preference of $0.10 per share over the BPS Series B common stock, which is held primarily by officers and current and former employees. BPS has raised an aggregate of $3.5 million from the sale of 1,444,721 shares of Series A preferred stock and 555,930 shares of Series B preferred stock. Each share of BPS Series B preferred stock and each share of BPS Series A preferred stock is entitled to receive $1.75 in preference to the shares of common stock upon a liquidation or sale of BPS.

BPS borrowed $2.5 million from us pursuant to a convertible secured promissory note dated September 1, 2009. On December 1, 2010, the note was converted into 1,785,714 shares of BPS Series B preferred stock at a price of $1.40 per share, which represents a 20% discount to the price per share paid by other purchasers of Series B preferred stock. Upon conversion of the note into Series B preferred stock, the Company owned 64% of the common stock assuming the conversion of all Series A and Series B preferred stock into Series B common stock.

BPS has entered into government contracts under which it recognized revenue of $734,000 in 2009, $1.6 million in 2010, and $968,000 in the six months ended June 30, 2011.

Prior to the closing of our acquisition of the minority interest in BPS, BPS maintained an independent stock option plan. Pursuant to its plan, Gordon Link was granted an option to purchase up to 30,000 shares of Series B common stock at an exercise price of $0.10 per share on September 18, 2008 and Ken Lynn was granted an option to purchase up to 30,000 shares of Series B common stock at an exercise price of $0.10 per share on January 20, 2009. The following options to purchase Series B common stock were exercised at $0.05 per share in September 2006 and purchased by the following officers and/or directors of the Company:

Name	Shares
Charles J. Link, Jr., M.D.	1,500,000
Nicholas N. Vahanian, M.D.	400,000
Thomas A. Raffin, M.D.	50,000
Ernest J. Talarico, III	50,000

Dr. Charles Link and Dr. Vahanian delivered notes to BPS in the principal amounts of $75,000 and $20,000, respectively, in September 2006, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under the stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation—Indebtedness of Management and Related Agreements." Dr. Link serves as CEO of BPS, and Dr. Vahanian serves as Chief Medical Officer of BPS.

Acquisition of BioProtection Systems Corporation

On January 7, 2011, we acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of ours with BPS, with BPS as the surviving corporation. In connection with this transaction, we issued an aggregate of 276,304 shares of our Series E preferred stock to the former holders of BPS Series B common stock, BPS Series A preferred stock and BPS Series B preferred stock (other than the Company). 221,066 of the shares of our Series E preferred stock were issued to the holders of the BPS Series B common stock, BPS Series A preferred stock and BPS Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of our Series E preferred stock were issued on August 12, 2011, there being no indemnity claims made under the merger agreement. As a result of this transaction, BPS became a wholly-owned subsidiary of the Company and our note was converted into Series B preferred stock of BPS. All options to purchase shares of BPS stock became options to purchase a total of 106,347 shares of our common stock.

In connection with this transaction, shares of our Series E preferred stock were issued to our officers and directors as follows:

Name	Shares of Series E Preferred Stock Issued at Closing of the Merger	Shares of Series E Preferred Stock Issued August 12, 2011
Charles J. Link, Jr., M.D.	41,568	10,392
Nicholas N. Vahanian, M.D.	11,085	2,771
Thomas A. Raffin, M.D.	1,386	346
Ernest J. Talarico, III	1,386	346

In addition, the following directors and officers of NewLink who are also directors or officers of BPS exchanged their BPS stock options for options to acquire shares of NewLink common stock as follows:

Name	Options to Acquire BPS Series B Common Stock	Options to Acquire NewLink Common Stock
Charles J. Link, Jr., M.D.	20,000	5,385
Nicholas N. Vahanian, M.D.	20,000	5,385
Thomas A. Raffin, M.D.	50,000	13,462
Ernest J. Talarico, III	45,000	12,116

The acquisition of BPS was recommended by a special committee of our Board of Directors consisting of Dr. Alexander and Messrs. Lundquist and Saluri, none of whom served as directors of BPS. Dr. Alexander and Mr. Saluri did not own any shares or options in BPS. The David Lundquist Revocable Trust owned shares of Series A Preferred Stock in BPS.

Related Party Transactions

In connection with his employment with us, Mr. Gordon Link was required to relocate from Colorado to Iowa. Pending the sale of his home in Colorado, we agreed to loan him the funds necessary to purchase a new home. He borrowed $500,000 from us on July 28, 2008, which bore interest at the IRS applicable federal rate of 2.42% per annum. As of May 11, 2010, Mr. Link had repaid the principal on the loan and accrued interest of $10,052 was forgiven.

On May 2, 2008, Dr. Charles Link borrowed $225,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2009. On January 22, 2009, we granted Dr. Link a bonus of $78,149, which was applied to the principal due on the loan. On April 24, 2009, Dr. Link repaid the remaining principal and accrued interest on the loan.

On April 24, 2009, Dr. Link borrowed $350,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due May 1, 2011. On May 7, 2010, the note plus accrued interest of $25,170 was forgiven, effective as of July 2, 2010, and an additional bonus of $180,226 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options held by Dr. Link to purchase our common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid, and Dr. Link agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

Dr. Vahanian borrowed $31,500 from us at an interest rate of 6.71% per annum. On July 1, 2010, the note plus accrued interest of $10,000 was forgiven, effective as of July 2, 2010, and a bonus of $12,010 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options held by Dr. Vahanian to purchase our common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid, and Dr. Vahanian agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

On August 20, 2008, Dr. Vahanian borrowed $125,000 from us at an interest rate of 6% per annum, with all accrued interest and principal due March 1, 2009. On January 22, 2009, we granted Dr. Vahanian a bonus of $55,037, which was applied to the principal due on the loan. On April 24, 2009, Dr. Vahanian repaid the remaining principal and accrued interest on the loan.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under Securities and Exchange Commission, or SEC, rules.

Recent Accounting Pronouncements

In April 2009, the Financial Accounting Standards Board, or FASB, issued guidance that expands the fair value disclosures required for financial instruments to interim reporting periods for publicly traded companies, including disclosure of the significant assumptions used to estimate the fair value of financial instruments. We adopted this guidance effective June 30, 2010. The adoption did not impact our financial position or results of operations.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The amended guidance requires disclosure of transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy, including the reasons and the timing of the transfers and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of the assets and liabilities measured under Level 3 of the fair value measurement hierarchy. The Company adopted the new disclosure requirements on January 1, 2010, except for the requirement concerning gross presentation of Level 3 activity, which is effective for fiscal years beginning after December 15, 2010. The adoption of the Level 1 and Level 2 disclosure guidance did not have an impact on the Company's consolidated financial position or results of operations.

In recent exposure drafts, the International Accounting Standards Board (IASB) and the FASB proposed a new approach to the accounting for leases. From a lessee's perspective, the exposure drafts propose to abolish the distinction between operating and finance/capital leases. In its place, a right-of-use model would be used. This proposal, as currently written, would require the lessee to recognize an asset for its right to use the underlying leased asset and a liability for its obligation to make lease payments. This would lead to an increase in assets and liabilities for leases currently classified as an operating lease and could also lead to a change in timing as to when the expense is recognized. This exposure draft is not yet finalized.

In June 2011, the FASB issued Accounting Standards Update ASU 2011-05, an amendment of the Codification Topic 220, *Comprehensive Income*. ASU 2011-05 increases the prominence of items reported in other comprehensive income and eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. ASU 2011-05 requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 will be effective retrospectively for fiscal years, and interim periods within those years, beginning after December 15, 2011, with earlier adoption permitted. ASU 2011-5 is effective for the Company beginning January 1, 2012. The adoption of ASU 2011-05 will not have a material effect on the Company's financial statements.

Internal Control Over Financial Reporting

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

For the year ending December 31, 2011, pursuant to Section 404 of the Sarbanes-Oxley Act, management will be required to deliver a report that assesses the effectiveness of our internal control over financial reporting. Under current SEC rules, our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2012, unless we qualify for an exemption as a non-accelerated filer under the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted on July 21, 2010.

Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share

We calculated net loss per share in accordance with Accounting Standards Codification (ASC) 260, *Earnings per Share*. We have determined that the Series A, Series AA, Series AAA, Series B, Series BB, Series C and Series D preferred stock represent participating securities in accordance with ASC 260. However, since we operate at a loss, and losses are not allocated to the preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss for all periods presented; accordingly, the inclusion of common stock options and warrants would be anti-dilutive.

Dilutive common stock equivalents would include the dilutive effect of convertible securities, common stock options, warrants for convertible securities and warrants for common stock equivalents. Potentially dilutive common stock equivalents total approximately 23.4 million, 21.2 million, 17.9 million and 11.4 million as of June 30, 2011 and December 31, 2010, 2009 and 2008, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect. Therefore, the weighted average shares used to calculate both basic and diluted earnings per share are the same.

Quantitative and Qualitative Disclosures About Market Risks

We are exposed to market risk related to changes in interest rates. As of June 30, 2011 and June 30, 2010, we had cash and cash equivalents and certificates of deposit of $9.8 million and $10.8 million, respectively, consisting of money market funds and bank certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in short-term marketable securities. Our certificates of deposit are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our certificates of deposit until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial (or no) impact on our financial statements.

BUSINESS

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve cancer treatment options for patients and physicians. Our portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. Our lead product candidate, HyperAcute Pancreas cancer immunotherapy, or HyperAcute Pancreas, is being studied in a Phase 3 clinical trial in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. We initiated this trial based on encouraging interim Phase 2 data that suggests improvement in both disease-free and overall survival. We have also received Fast Track and Orphan Drug designations from the FDA for this product candidate for the adjuvant treatment of surgically-resected pancreatic cancer. We have three additional product candidates in clinical development, including our HyperAcute Lung cancer immunotherapy, or HyperAcute Lung, which is being studied in a Phase 1/2 clinical trial conducted at the National Cancer Institute, or NCI, and our HyperAcute Melanoma cancer immunotherapy, or HyperAcute Melanoma, which is being studied in an investigator-initiated Phase 2 clinical trial. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients either as a monotherapy or in combination with other therapies and have demonstrated a favorable safety profile.

Our HyperAcute product candidates are based on our proprietary HyperAcute immunotherapy technology, which is designed to stimulate the human immune system. Our HyperAcute product candidates use allogeneic (non-patient specific) cells from previously established cell lines rather than cells derived from the patient. We believe our approach enables a simpler, more consistent and scalable manufacturing process than therapies based on patient specific tissues or cells. Our product candidates are designed with an objective to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens, without incremental toxicity. We are also conducting small-molecule based research and development with an aim to produce new drugs capable of breaking the immune system's tolerance to cancer through inhibition of the indoleamine-(2,3)-dioxygenase, or IDO, pathway. We are currently studying our lead IDO pathway inhibitor product candidate, d-1-methyltryptophan, or D-1MT, in collaboration with the NCI, in two Phase 1B/2 clinical trials. We believe that our immunotherapeutic technologies will enable us to discover, develop and commercialize multiple product candidates that can be used either alone or in combination with current therapies to treat cancer.

Our HyperAcute Cancer Immunotherapy Product Candidates

We initiated our Phase 3 clinical trial for HyperAcute Pancreas in May 2010. We expect to evaluate approximately 700 surgically-resected pancreatic cancer patients in this clinical trial and have enrolled 161 patients at 52 clinical sites in the United States as of September 1, 2011. We plan to complete the first and second interim analyses of data from our Phase 3 clinical trial for HyperAcute Pancreas in late 2012 and 2013, respectively, and to complete patient enrollment in 2013.

The interim data from our fully-enrolled 70-patient Phase 2 pancreatic cancer clinical trial suggests that HyperAcute Pancreas may improve disease-free and overall survival when given in addition to standard-of-care treatment to patients following complete resection of detectable disease. As of May 10, 2011, all patients had reached at least 12 months of follow-up with a median follow-up period of approximately 21 months. The study met its primary objective with an established median disease-free survival of 14.2 months. The most recent analyses of the secondary endpoint of overall survival showed one-year overall survival to be 86%. As of May 10, 2011, interim efficacy data for the 26 patients receiving high dose therapy demonstrated median disease-free survival of 15.3 months and a one-year overall survival rate of 96%. To date, HyperAcute Pancreas has demonstrated good tolerability and a favorable

safety profile. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Pancreas were injection site reaction (58%), fatigue (20%), induration (17%), nausea (8%), pruritus (7%), fever (7%), urticaria (6%), anemia (6%) and decreased white blood cell count (6%). There have been no reported grade four adverse events attributed to HyperAcute Pancreas, and less than 8% of the patients treated with HyperAcute Pancreas have experienced a grade three serious adverse event characterized by the investigators as possibly or probably attributable to our product candidate. The NCI's common terminology criteria, or CTC, categorizes adverse events into five grades, where grade one is mild, grade two is moderate, grade three is severe, grade four is life-threatening and grade five is death.

Our second most advanced product candidate, HyperAcute Lung, is in a Phase 1/2 clinical trial that is fully enrolled with 54 patients for the treatment of refractory, recurrent or metastatic nonresectable non-small cell lung cancer, or NSCLC. We performed an interim analysis of the 28 patients evaluated in the Phase 2 portion of the study on December 9, 2010, which showed median overall survival of 11.3 months and a one-year survival rate of 46%. Based on our analysis of data from comparable precedent clinical trials of similar patients, we would have expected a median overall survival of approximately eight months. In an interim analysis of 45 patients, HyperAcute Lung demonstrated a favorable safety profile and no dose limiting toxicities. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Lung were injection site reaction (92%), induration (56%), fatigue (25%), urticaria (12%), anemia (7%), pruritus (7%), lymphopenia (7%), elevated serum amylase (5%), edema (5%), skin pain (5%) and dyspnea (5%). There have been no reported CTC grade four adverse events attributed to HyperAcute Lung and less than 13% of the patients treated with HyperAcute Lung have experienced a CTC grade three serious adverse event characterized by the investigators as possibly or probably attributable to our product candidate. This trial is being conducted at the NCI. We are currently evaluating alternative designs for a Phase 2B/3 clinical trial in NSCLC with an adaptive design, which we plan to initiate in the first half of 2012 and on which we plan to complete the first interim analysis in 2013.

Our HyperAcute Melanoma product candidate is being studied in an investigator-initiated, fully enrolled 25 patient Phase 2 clinical trial for the treatment of advanced melanoma in combination with an eight-week course of PEG-Intron, a man-made immune modulator. As of September 8, 2011, interim analysis shows encouraging results, with all of the patients developing low levels of autoimmune antibodies and four out of 25 patients developing vitiligo. Vitiligo is an autoimmune condition in which the patient's immune system attacks melanoctyes in the skin, which are the cells that may turn into melanoma cancer cells. Vitiligo has previously been correlated with a favorable response to therapy in other melanoma immunotherapy studies. To date, HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile, with no systemic, drug-related serious adverse events characterized by the investigators as possibly or probably attributable to our product candidate. The most common non-serious adverse events reported were local injection site skin reactions, induration, diarrhea and nausea. We anticipate announcing results of the completed clinical trial in the second half of 2011. We anticipate initiating a Phase 2B clinical trial in melanoma in 2012.

Our HyperAcute Cancer Immunotherapy Technology

We believe our HyperAcute immunotherapies operate by exploiting a natural barrier present in humans that protects against infection being transmitted from other mammals. This barrier is related to the enzyme, alpha (1,3) galactosyl transferase, or a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called alpha (1,3) galactosyl carbohydrates, or a-Gal, on the surface of affected cells. Introducing a-Gal-expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal. Antibodies directed against the a-Gal epitope are potentially the most abundant natural antibody in humans and represent approximately 1% of circulating human antibodies.

Our HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens, or TAAs, common to both the immunotherapy and the patient's tumor cells.

We believe our proprietary HyperAcute immunotherapy technology offers several advantages over prior immunotherapy approaches. Specifically, our HyperAcute immunotherapy technology is designed to:

- harness the human body's innate immune response to a-Gal to fight cancer;
- utilize a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- use allogeneic (non-patient specific) cells from previously-established cell lines, which enables a simpler, more consistent and scalable manufacturing process than therapies based on autologous (patient specific) tissues or cells.

Our IDO Pathway Inhibitor Product Candidate

In addition to our HyperAcute product candidates, we are developing D-1MT, a small-molecule, orally bioavailable product candidate designed to inhibit the IDO pathway. In preclinical models, IDO pathway inhibitors have shown anti-tumor effects in combination with radiotherapy, chemotherapy, targeted therapy or immunotherapy. Through our collaboration with the NCI, we are studying D-1MT in two Phase 1B/2 safety and efficacy clinical trials in various chemotherapy and immunotherapy combinations. One clinical trial combines D-1MT with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The other clinical trial involves the combined use of D-1MT and Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care treatment, such as metastatic breast, prostate, ovarian and lung cancers. We anticipate announcing preliminary data from these clinical trials by the end of 2011.

Investment Highlights

We are a biopharmaceutical company with a pipeline of product candidates based on our proprietary immunotherapeutic technologies that are intended to address significant unmet medical needs in the treatment of cancer. We believe the following are the key attributes of our company:

Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial based on encouraging interim Phase 2 survival data in surgically-resected pancreatic cancer patients. We are currently enrolling patients in a Phase 3 clinical trial of our lead product candidate, HyperAcute Pancreas, which is being performed under an SPA with the FDA. If approved, we believe the addition of HyperAcute Pancreas as an adjuvant therapy has the potential to be an important component of treatment for surgically-resected pancreatic cancer, an indication with high mortality rates and limited treatment alternatives. The Phase 2 clinical trial for HyperAcute Pancreas met its primary objective with an established median disease-free survival of 14.2 months. The most recent analyses of the secondary endpoint of overall survival showed one-year overall survival to be 86%. As of May 10, 2011, interim efficacy data for the 26 patients receiving high dose HyperAcute Pancreas immunotherapy demonstrated a median disease-free survival of 15.3 months and a one-year overall survival rate of 96%. Median overall survival has not yet been reached for this population. We have also received Fast Track and Orphan Drug designations for this product candidate.

Our novel HyperAcute immunotherapy technology has a wide range of anti-cancer applications including two additional product candidates, HyperAcute Lung and HyperAcute Melanoma, in active clinical development. We believe our technology is broadly applicable to many types of solid tumors. We have fully enrolled both a 54-patient Phase 1/2 clinical trial for our HyperAcute Lung product candidate in NSCLC at the NCI as well as an investigator-initiated, 25-patient Phase 2 clinical trial for our HyperAcute Melanoma product candidate in advanced melanoma. In addition, we are evaluating our HyperAcute technology in preclinical models for the treatment of other cancer types. To date, our HyperAcute product candidates have been dosed in more than 200 cancer patients and have demonstrated good tolerability and a favorable safety profile.

We have in-house manufacturing capabilities for our HyperAcute product candidates that we believe are sufficient to support clinical development and initial commercialization of HyperAcute Pancreas in the United States. Our HyperAcute product candidates rely on established cell lines and can be produced at our current facility in Ames, Iowa through a cost-effective and scalable production process. Our HyperAcute product candidates do not require patients to donate cellular material, which permits an easier scale-up of the manufacturing process as compared to autologous therapies. We believe that our current and planned manufacturing facilities will be adequate to supply the initial commercial quantities of HyperAcute Pancreas, if approved, in the United States.

Our lead IDO pathway inhibitor product candidate is in clinical development in combination with multiple alternative therapies, including Taxotere. Our lead IDO pathway inhibitor drug candidate is D-1MT, which is currently being evaluated in two Phase 1B/2 clinical trials co-sponsored by the NCI. The first clinical trial combines D-1MT with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. The second clinical trial combines D-1MT with Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. D-1MT has shown favorable drug-like properties and has demonstrated anti-tumor activity in animal models in combination with traditional chemotherapy. We are also conducting preclinical research to identify new IDO pathway inhibitors.

We have an extensive intellectual property portfolio. We own or license 69 issued/granted patents, including those validated internationally, and 61 pending United States and foreign patent applications covering six patent families relating to HyperAcute technology, 19 patent families relating to IDO inhibitor immune response modulators and five other patent families not related to either our HyperAcute technology or IDO product candidates. We believe the intellectual property pertaining to our HyperAcute technology offers broad protection in this field. In addition, we believe we have broad protection pertaining to immune response modulators, with market exclusivity for the use of D-1MT to treat cancer until 2027 in the United States.

Our Strategy

Our strategy is to discover, develop and commercialize immunotherapeutic products for the treatment of cancer where the needs of patients are unmet by current therapies. The critical components of our business strategy include:

Complete the Phase 3 clinical trial of HyperAcute Pancreas, our lead immunotherapy product candidate, and gain regulatory approval. HyperAcute Pancreas is currently in Phase 3 clinical development in patients with surgically-resected pancreatic cancer. This clinical trial, which was initiated in May 2010, is an approximately 700-patient randomized clinical trial being performed under an SPA with the FDA. We have enrolled 161 patients at 52 clinical sites in the United States as of September 1, 2011. We plan to complete the first and second interim analyses in late 2012 and 2013, respectively, and to complete patient enrollment in 2013.

Develop sales and marketing infrastructure to commercialize our HyperAcute Pancreas product candidate in the United States and establish commercial partnerships in other regions. We currently own or exclusively license all rights to our HyperAcute product candidates. We intend to commercialize some or all of our HyperAcute product candidates, including HyperAcute Pancreas, in the United States by building an initial specialty sales force of approximately 50 to 100 representatives with a focused marketing effort directed to medical and surgical oncologists. We intend to seek collaborations to develop and commercialize our HyperAcute product candidates outside of the United States, and may seek collaborations for selected indications within the United States.

Advance our HyperAcute Lung and HyperAcute Melanoma product candidates through additional clinical trials. Based on the clinical trial data generated to date by HyperAcute Lung and HyperAcute Melanoma, we plan to pursue further clinical development of these product candidates. We have convened a panel of thought leaders in lung cancer to assist us in planning a Phase 2B/3 clinical trial for NSCLC with an adaptive design, which we plan to initiate during the first half of 2012. We are also currently working to develop clinical trial designs to further study the efficacy of HyperAcute Melanoma either as a stand-alone or combination therapy and we plan to initiate a Phase 2B clinical trial in 2012.

Expand our manufacturing capabilities for our HyperAcute product candidates. We manufacture HyperAcute Pancreas at our facility in Ames, Iowa and believe our current and planned manufacturing facilities will be adequate to support the initial U.S. commercialization efforts for that product. We intend to maintain control over manufacturing for our HyperAcute product candidates for the U.S. market and may need to expand our manufacturing capacity in the future if more than one of our products are approved.

Investigate our HyperAcute technology in additional oncology indications. We have developed a process to discover and develop new tumor-specific HyperAcute cancer immunotherapies. In addition to our lead programs in pancreatic cancer, lung cancer and melanoma, we intend to pursue clinical development of this technology in other tumor types.

Develop and commercialize D-1MT, a small-molecule product candidate, in cancer. In collaboration with the NCI, we have initiated two Phase 1B/2 clinical trials to evaluate use of D-1MT in combination with other approved therapies for solid tumor indications. We also plan to initiate multiple clinical trials of our D-1MT product candidate in combination with other approved and development-stage cancer therapies, including immunotherapies such as our HyperAcute Lung and HyperAcute Melanoma product candidates.

Cancer Market Overview

Cancer is the second-leading cause of death in the United States with an estimated 569,000 deaths in 2010 according to the American Cancer Society. Despite a number of advancements in the diagnosis and treatment of cancer over the past decade, overall five-year survival rates from all cancer types is 68% for the period spanning 1999-2005 according to the American Cancer Society.

Cancer is characterized by abnormal cells that grow and proliferate, forming masses called tumors. Under certain circumstances, these proliferating cells can metastasize, or spread, throughout the body and produce deposits of tumor cells called metastases. As the tumors grow, they may cause tissue and organ failure and, ultimately, death. To be effective, cancer therapies must eliminate or control the growth of the cancer.

The specialized cells of the immune system recognize specific chemical structures called antigens. Generally, foreign antigens trigger an immune response that results in the removal of disease-causing agents from the body. Cancer cells, however, frequently display antigens that are also found on normal cells. The immune system may not be able to distinguish between tumors and normal cells and, thus, may

be unable to mount a strong anti-cancer response. Tumors also have various defense mechanisms that may prevent the immune system from fully activating.

Current therapies, such as surgery, radiation, hormone treatments and chemotherapy, do not address this evasive characteristic of cancer and may not have the desired therapeutic effect. Active immunotherapies stimulate the immune system, the body's natural mechanism for fighting disease, and may overcome some of the limitations of current standard-of-care cancer therapies.

Limitations of Current Cancer Therapies

We believe current cancer treatment alternatives suffer from a number of limitations that impair their effectiveness in improving patient survival and overall quality of life including:

- *Toxicity.* Chemotherapeutic agents are highly toxic to the human body and often cause a variety of side effects, which may include nausea and vomiting, bleeding, anemia and mucositis. Targeted therapeutics may have fewer systemic toxicities, but still tend to have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These effects limit a patient's ability to tolerate treatment thereby depriving the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once educated as to the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, patients diagnosed with terminal cancer often choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer often cannot tolerate cancer therapy, and certain therapies have been shown to hasten death in some cases as the patient's health deteriorates.
- *Mechanism of action.* While many current therapeutic approaches may be effective against a particular target, the overall impact of these therapies on treating cancer is limited because the abundance and diversity of tumor cells are believed to enable cancers to adapt and become resistant to these treatments over time resulting in reduced longer-term efficacy.
- *Short-term approach.* Incremental survival benefit is the primary objective of many currently marketed and development-stage cancer therapeutics. In general, many drugs show modest impact on overall survival or only affect progression-free survival. Other than surgical tumor removal, curative intent is often not a focus or realistic potential outcome of many current cancer therapies.
- *Immune system suppression.* Cancer is difficult to treat in part because cancer cells use sophisticated strategies to evade the immune system. Current approaches to cancer treatment generally involve introduction of an agent, such as a chemical, an antibody or radiation. These agents cause cell apoptosis (programmed cell death) or inhibit the proliferation of all cells, including immune cells, thereby indirectly suppressing the immune system. A weakened immune system not only further inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases.

Our Potential Solution: HyperAcute Immunotherapy

We believe our HyperAcute immunotherapy has the following advantages over existing therapies, which may enable us to develop commercial products that extend both survival and quality of life for cancer patients:

- *Robust, innate immune response.* Our HyperAcute immunotherapy technology is designed to fight cancer by activating the human body's naturally protective and rapid immune response to the a-Gal carbohydrate.
- *Complex, multi-targeted approach.* We believe our HyperAcute immunotherapy technology attacks cancer through several mechanisms. Initially, by introducing allogeneic, whole cancer cells incorporating a-Gal to the body, our HyperAcute immunotherapy is designed to teach the immune system to attack specific cancer cells, such as pancreas, lung or melanoma cancer cells, with both

antibody mediated and cellular immune responses. Secondly, by using multiple whole cancer cell lines, our HyperAcute immunotherapy targets multiple tumor proteins simultaneously, which we believe increases the probability of stimulating an effective immune response to the heterogeneous cells that are present in cancer.

- *Favorable safety profile.* We have not observed significant additional systemic toxicities when HyperAcute immunotherapy has been added to chemotherapy regimens. There have been no CTC grade four serious adverse events attributed to HyperAcute Pancreas, HyperAcute Lung or HyperAcute Melanoma. Our HyperAcute immunotherapy technology is designed to stimulate a natural immune response to specific cancer cells with the objective to decrease the risks of off-target effects. Data generated to date suggests that patients can tolerate the addition of our HyperAcute product candidates to standard chemotherapy and radiation therapy.
- *Broad applicability.* We believe that the novel mechanism of action, good tolerability and favorable safety profile will enable our HyperAcute product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies. Our HyperAcute immunotherapy technology can be targeted to additional specific tumor types by modifying cells from the cancer type of interest.
- *Potential application as single agent adjuvant therapy.* We believe many patients who are too ill to tolerate chemotherapy due to the associated toxicities may be able to benefit from our HyperAcute product candidates. We also believe that the safety profile of our HyperAcute immunotherapies may make them suitable for use in patients with low risk of recurrence or metastasis who choose not to receive chemotherapy due to its toxicity relative to the potential therapeutic benefits.

Our Product Pipeline

The chart below summarizes our current product candidates and their stages of development.

Product Candidate	Phase of Development	Indication	Upcoming Milestone
HyperAcute Immunotherapy Technology			
HyperAcute Pancreas	Phase 3	Adjuvant to standard-of-care in surgically-resected pancreatic cancer	End of 2012: 1st interim analysis 2013: 2nd interim analysis 2013: Complete enrollment
HyperAcute Lung	Phase 1/2 enrollment complete	Advanced NSCLC	1st half 2012: Initiate Phase 2B/3 clinical trial
HyperAcute Melanoma	Phase 2 enrollment complete(1)	Advanced melanoma in combination with PEG-Intron	2013: 1st interim analysis 2nd half 2011: Update Phase 2 clinical trial results 2012: Initiate Phase 2B clinical trial
Additional HyperAcute cancer immunotherapies	Lead optimization	To be determined	2012: Initiate Phase 1 clinical trial
IDO Pathway Inhibitor Technology			
D-1MT	Phase 1B/2(2)	2nd-line metastatic solid tumors in combination with p53 adenovirus	End of 2011: Announce preliminary data
	Phase 1B/2(2)	2nd-line metastatic solid tumors in combination with Taxotere	End of 2011: Announce preliminary data
Additional IDO Pathway Inhibitor Candidates	Lead optimization	To be determined	To be determined

(1) Investigator-initiated

(2) Co-sponsored by the National Cancer Institute

Our HyperAcute Pancreas Cancer Immunotherapy Product Candidate

Our lead product candidate, HyperAcute Pancreas, is in a Phase 3 clinical trial being performed under an SPA with the FDA. We have also received Fast Track and Orphan Drug designations for this product candidate for the adjuvant treatment of surgically-resected pancreatic cancer. HyperAcute Pancreas consists of equal doses of two separate allogeneic pancreatic cancer cell lines engineered to express a-Gal. Although cells making up naturally occurring pancreatic tumors in patients do not express a-Gal, the tumor cells share other molecules, called tumor-specific or tumor-associated antigens, with the genetically altered pancreatic cancer cells contained in HyperAcute Pancreas. We believe the molecules that are shared by both the patient's tumor cells and HyperAcute Pancreas immunotherapy cells allow the antibodies and immune cells that develop against the HyperAcute Pancreas immunotherapy cells to target and destroy the patient's own tumor cells as well. Each of the modified cell lines is grown in large cultures, harvested, irradiated and packaged. Approximately 150 million cells of each HyperAcute Pancreas cell line are given by intradermal injection with each treatment. A series of up to 12 treatments using both cell lines over a period of six months was used in our Phase 2 clinical trial. In our Phase 3 protocol, we are adding an additional series of six maintenance treatments, to be given during the next six months.

Market Opportunity

The American Cancer Society estimates that approximately 43,000 new cases of pancreatic cancer were diagnosed in the United States in 2010. Pancreatic cancer has generally been recognized as an aggressive form of cancer with non-specific initial symptoms, making it difficult to diagnose at an early stage. Due to the difficulty in diagnosis and the aggressive nature of this cancer, the National Cancer Institute estimates a 96% mortality rate is associated with this disease, and the American Cancer Society estimates one-year and five-year overall survival rates of about 24% and 5%, respectively.

Pancreatic cancer can generally be divided into three broad categories: (1) local disease, in which the cancer is confined to the pancreas and can be removed surgically, which is called resection; (2) locally advanced disease, in which the cancer has spread locally and may or may not be eligible for resection because it has invaded tissues that should not be removed, such as key nerves and arteries; and (3) metastatic disease, in which the tumor has spread beyond the region of the pancreas.

According to eMedicine, a healthcare reference website run by WebMD containing peer-reviewed articles on diseases and medical topics, approximately 20% of pancreatic cancer patients in the United States are eligible for resection at initial diagnosis. These earlier stage, resected patients have significantly better prognoses than patients with later stage disease since they tend to have better nutritional and immune status and significantly lower amounts of micro-metastatic and residual disease. A study published in the *Journal of the American Medical Association*, or *JAMA*, in March 2008 showed that resection followed by chemotherapy or chemoradiotherapy, known as adjuvant therapy, extends median survival to approximately 18 months. We believe the addition of HyperAcute Pancreas to adjuvant standard-of-care has the potential to improve median disease-free survival and overall survival in resected pancreatic cancer patients.

Patients with locally advanced nonresectable disease represent an additional 30% of patients at diagnosis and are generally treated with chemotherapy or chemoradiotherapy. We plan to initiate a clinical trial to test the safety and efficacy of HyperAcute Pancreas in locally advanced, nonresectable pancreatic cancer patients. We believe patients with locally advanced nonresectable disease may also benefit from the addition of HyperAcute Pancreas to standard-of-care.

Clinical Trials

Phase 3 Clinical Trial

In May 2010, we initiated our Phase 3 clinical trial for HyperAcute Pancreas. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating approximately 700 Stage I and Stage II surgically-resected pancreatic cancer patients, according to the American Joint Committee on

Cancer classification system, or AJCC system, who have no detectable disease by a CT scan. The primary endpoint of the clinical trial is overall survival, with secondary endpoints of disease-free survival, safety, toxicity and immunological responses. Based on our discussions with the FDA, we plan to enroll up to 722 patients and believe this number of patients will enable us to demonstrate statistically significant improvement in median overall survival at the end of the trial. Additional patients will be accrued, if needed, to maintain adequate numbers for statistical significance. As of September 1, 2011, 161 patients had been enrolled at 52 U.S. based clinical sites. We are actively recruiting additional major medical centers, with high volume of pancreatic cancer surgeries, to participate in this clinical trial.

Current adjuvant standard-of-care regimens for post-resection pancreatic cancer patients include gemcitabine alone or a combination of gemcitabine plus 5-FU based chemoradiotherapy. In our Phase 3 clinical trial, 50% of the patients will receive standard adjuvant therapy with HyperAcute Pancreas and 50% will receive standard adjuvant therapy without HyperAcute Pancreas. Data from our Phase 2 clinical trial demonstrated a statistically significant improvement in disease-free survival at one year for the high dose (300 million cells) arm of the study. Therefore, we selected the 300 million cell dose as the treatment dose for our Phase 3 clinical trial. In addition, we reasoned empirically that considering the observed dose response, higher doses of treatment might provide further benefit. We therefore modified the treatment schedule for all patients receiving HyperAcute Pancreas to increase the number of immunotherapy treatments from 12 to up to 18 treatments given every two weeks over a period of approximately six months followed by six monthly injections. Patients in the study are being monitored with periodic imaging to check for recurrences for at least five years after surgery or until death occurs.

The clinical trial includes interim evaluations for both overall survival and disease-free survival when approximately one-half of the expected number of deaths have occurred and, if needed, again when approximately three-quarters of the expected number of deaths have occurred. Our SPA specifies that if results show a highly statistically significant effect on survival we may stop the trial and apply for marketing approval. Our statistical modeling indicates that a 45% or 30% improvement in overall survival, relative to controls through the period when one-half or three-quarters, respectively, of the expected number of deaths have occurred, would be highly statistically significant. Overall survival refers to the duration of life after surgery. Disease-free survival refers to the period of time after surgical resection when no evidence of disease is detected.

When initially diagnosed, patients eligible for our Phase 3 clinical trials have localized tumors that can potentially be completely removed based upon strict imaging criteria. In addition, the patients are generally strong enough to survive a major surgical procedure that involves an inherent significant risk of death. Patients are not eligible to participate in this trial until pathology and post-operative imaging studies indicate that they are without clinical evidence of residual tumor as observed by a CT scan. As a result, patients admitted to the trials have minimal residual tumor burden and possess generally intact immune systems, characteristics that we believe improve the likelihood of meaningful response.

Phase 2 Clinical Trial

We have completed enrollment of a 70-patient open-label, two-armed Phase 2 clinical trial in which HyperAcute Pancreas was given in doses of either 100 million cells or 300 million cells approximately twice monthly for six months in combination with the standard-of-care treatment regimen, which consisted of gemcitabine chemotherapy plus 5-FU based chemoradiotherapy. We enrolled patients for this clinical trial at 16 different sites including some of the leading cancer centers in the United States. Patients in this clinical trial had been diagnosed with Stage I and Stage II pancreatic adenocarcinoma, according to the AJCC system, and subsequently underwent surgical resection to remove all visible tumors with curative intent. There were no other exclusion criteria relative to pre-operative disease status. The primary endpoint of this clinical trial was to evaluate disease-free survival with secondary endpoints of overall survival and toxicity. We enrolled the final patient in March 2010.

We designed this clinical trial to add HyperAcute Pancreas immunotherapy to the standard-of-care treatment regimen defined in RTOG 97-04 (Regine et al., 2008) as adjuvant 5-FU chemoradiotherapy plus gemcitabine and to perform a dose-finding analysis of cohorts receiving bi-weekly HyperAcute Pancreas doses of 100 million or 300 million cells. Our objectives are to demonstrate a clinical benefit by addition of HyperAcute Pancreas to RTOG 97-04 standard adjuvant therapy alone and to determine if a superior dosing regimen can be identified.

We enrolled 44 patients in the 100 million cell dose cohort, or low dose group, and 26 patients in the 300 million cell dose cohort, or high dose group. The baseline patient characteristics of both cohorts were similar in terms of age, gender and disease state.

As of May 10, 2011, all patients had reached at least 12 months of follow-up with a median follow-up period of approximately 21 months. To date, HyperAcute Pancreas has demonstrated good tolerability and a favorable safety profile. There have been no reported CTC grade four adverse events attributed to HyperAcute Pancreas, and less than 8% of the patients treated with HyperAcute Pancreas have experienced a CTC grade three serious adverse event characterized by the investigators as possibly or probably attributable to the product candidate. The most common non-serious adverse events observed were fatigue, local injection site skin reactions and injection site pain. The nature and frequency of the adverse events observed in this clinical trial are consistent with the adverse events observed in all clinical trials for HyperAcute Pancreas. When HyperAcute Pancreas was given in combination with gemcitabine and 5-FU based chemoradiotherapy, approximately 4% of patients experienced CTC grade three lymphopenia, 3% of patients experienced CTC grade three pain, less than 2% of patients experienced CTC grade three pancreatitis and less than 2% experienced CTC grade three fatigue, adverse events possibly or in the case of fatigue, probably attributable to our product candidate according to the principal investigators.

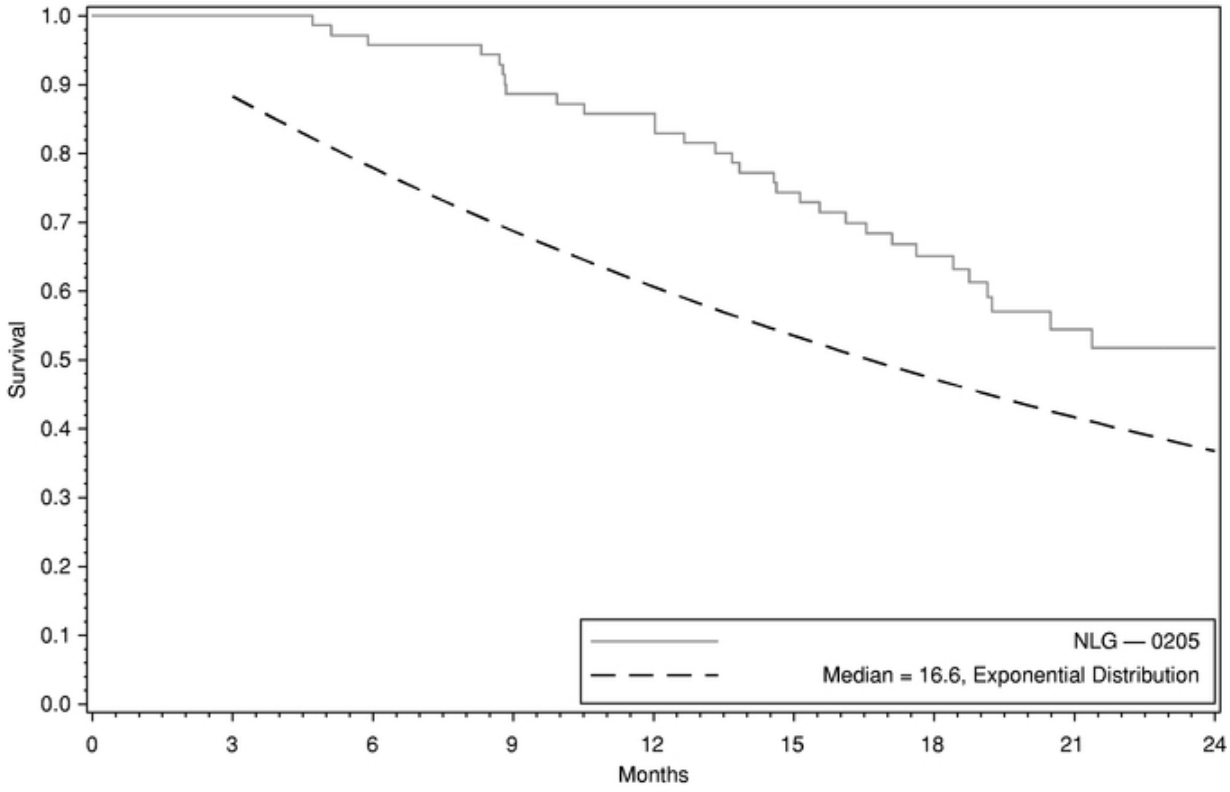
The study met its primary objective with an established median disease-free survival of 14.2 months. There was a statistically significant difference in disease-free survival at one year between the high and low dose groups (p=.02). The most recent analyses of the secondary endpoint of overall survival showed one-year overall survival to be 86% and a Kaplan-Meier estimate predicts a median overall survival at 24.4 months. Data from the high and low dose HyperAcute Pancreas treatment groups demonstrated a one-year disease-free survival of 81% and 52%, and a one-year overall survival rate of 96% and 80% for the respective cohorts. These results compare favorably to the outcomes of prior clinical trials in surgically resected pancreatic cancer patients. Of these clinical trials, we believe the study known as RTOG 97-04, a 538-patient (451 evaluable patients) clinical trial conducted by the Radiation Therapy Oncology Group, is the most comparable with respect to baseline patient characteristics and treatment regimen even though our trial population had a higher frequency of lymphatic node invasion (68% vs. 81% in our trial). One treatment arm in RTOG 97-04 received gemcitabine chemotherapy plus 5-FU based chemoradiotherapy, which is the current standard-of-care treatment regimen, and we believe this treatment arm provides the best comparison to our NLG-0205 study. In RTOG 97-04, the 221 patients in the standard-of-care treatment arm had one-year disease-free survival of less than 50% and a one-year overall survival rate of 69% based on Kaplan-Meier analysis.

Kaplan-Meier Analysis

Kaplan-Meier analysis is a statistical method of predicting survival rates. As shown in the graph below, the Kaplan-Meier-calculated overall survival in our Phase 2 clinical trial, referred to as NLG-0205, compares favorably to data from RTOG 97-04. The dotted line depicts overall survival of successfully resected pancreatic cancer patients derived from the published data of RTOG 97-04 in which the one year survival rate was 69% for the 221 patients receiving gemcitabine plus 5-FU based chemoradiotherapy. The solid line represents the Kaplan-Meier estimated survival curve for patients in our Phase 2 clinical trial as of May 10, 2011. At 12 months after surgery overall survival for the combined patient population in NLG-0205 is 86%. The Kaplan-Meier estimate of median overall survival is 24.4 months for the combined patient population in NLG-0205 versus 16.6 months predicted by the Memorial Sloan Kettering Cancer

Center nomogram (Brennan et al., 2005), as discussed below, of our actual patient characteristics and 18.8 months for RTOG 97-04 patients (based on 221 patients receiving gemcitabine plus 5-FU based chemoradiotherapy).

Kaplan-Meier Plot of Overall Survival for NLG-0205 Versus Expected Distribution



Data from the NLG-0205 study has been stratified into high dose and low dose groups on the basis of statistically significant differential responses to HyperAcute Pancreas immunotherapy. We believe 300 million cells is the largest practically attainable treatment dose based on clinician observation; however, we have tested a 100 million cell dose as a means to reduce the number of injections needed during therapy. The patterns of response in patients treated with these two doses have become distinct during the study.

Patients in the high dose group of NLG-0205 demonstrated an improved disease-free survival compared to patients in the low dose group or the current standard-of-care RTOG 97-04 chemoradiotherapy protocol alone. The median disease-free survival in NLG-0205 high dose patients is projected to be 15.3 months based on data as of September 1, 2011 versus an estimated median disease-free survival of 11.4 months for the 221 patients receiving gemcitabine plus 5-FU based chemoradiotherapy in RTOG 97-04. The apparent difference in disease progression is most prominent at earlier time points during active immunotherapy and persists beyond the completion of treatment.

The maturing data from NLG-0205 do not yet allow calculation of median overall survival but demonstrate a statistically significant difference between high and low dose groups in terms of disease-free survival (p=0.02). In addition, an increased overall survival at one year for 300 million cell dose patients is approaching (but has not yet achieved) the level of statistical significance observed compared to low dose patients (96% vs. 80%, p=0.053). These data demonstrate that patients in the high dose group have both a higher disease-free survival and a trend towards higher overall survival at one year compared to patients in the low dose group. Notably, patients treated at both dose levels in NLG-0205 compare favorably to the

63% one-year overall survival calculated by the Memorial Sloan Kettering Cancer Center nomogram (Brennan et al., 2005), as discussed below, of the NLG-0205 patient population. Furthermore, both dose levels in NLG-0205 compare favorably to the 69% one-year overall survival observed for the 221 patients who received gemcitabine plus 5-FU based chemoradiotherapy in the RTOG 97-04 study.

	Disease-Free Survival at 1 year	Overall Survival at 1 year
Brennan et al., 2005 nomogram	Not Applicable	63%
RTOG 97-04 (221 patients)	<50%*	69%
NLG-0205—100 million cell dose group	52%	80%
NLG-0205—300 million cell dose group	81%	96%

* Disease-free survival at 1 year was not reported. However, from the median disease-free survival of 11.4 months, we have inferred that disease-free survival at 1 year is less than 50%.

After reviewing these data that cumulatively suggest a significant dosage effect, we have amended our Phase 3 clinical trial protocol to increase the duration of therapy to 12 months in an effort to further delay recurrence and improve overall survival.

Analysis of Historical Controls

Baseline patient characteristics are key factors to consider in reviewing clinical trials. Not all patients have an identical disease state and, in the context of surgically-resected pancreatic cancer patients, certain patient characteristics have been shown to have a significant impact on a patient's prognosis of disease progression and survival. Prognostic indicators for Stage I/II pancreatic cancer have been analyzed during the development of the AJCC system. The principal prognostic indicators have been validated and demonstrate that baseline data on tumors, nodal involvement and metastasis inform meaningful predictions of likely outcomes for patients. These characteristics include:

Nodal status: refers to the presence of cancer in the nearby lymph nodes. When cancer enters the lymph nodes, there is an increased risk that the cancer will spread, or metastasize, to other regions of the body via the lymphatic system. As such, nodal status is an indicator of disease progression and thereby a prognostic indicator of survival. A study completed by Hsu et al. and published in the *Annals of Surgical Oncology* in 2010 reported that resected pancreatic cancer patients who received adjuvant chemoradiotherapy with positive lymph nodes prior to resection had a median overall survival 8.5 months less than that of patients with negative nodes. Further, a study conducted by Lim et al. published in *Annals of Surgery* in 2003 demonstrated that patients with greater than four positive lymph nodes had median overall survival 9.4 months less than that of patients with no positive lymph nodes.

Degree of local invasion: refers to the extension of tumors into peripancreatic tissues including neural, vascular, or lymphatic structures or surrounding organs. Larger, higher-staged tumors are associated with a higher degree of local invasion, advanced disease and a poorer prognosis. As it relates to pancreatic cancer, patients with smaller, less invasive tumors have a greater median overall survival as reported by Gebhardt et al. in *Langenbeck's Archives of Surgery* in 2000. In the Gebhardt study, patients with pancreatic cancer that had invaded the lymph vessels, blood vessels and perineural tissues had a median overall survival of 16.8 months, 7.2 months and 4.8 months less, respectively, than patients with cancer that had not invaded these tissues.

Tumor stage: refers to the size and peripancreatic extension of pancreatic cancer. T1 is defined as less than two centimeters in diameter and limited to the pancreas; T2 is defined as greater than two centimeters in diameter and limited to the pancreas; T3 is defined as a tumor that has extended beyond the pancreas; and T4 tumors are defined as unresectable. The T3 tumor stage is associated with poorer prognosis and increased risk of death compared to T1-T2 tumors in resected pancreatic

cancer patients who receive adjuvant chemoradiotherapy as reported by Hsu et al., where T3 patients had a median overall survival that was 8.3 months less than T1-T2 patients.

Tumor grade: refers to abnormalities of cancer cells relative to healthy cells. Tumor cells considered undifferentiated, or having a higher tumor grade, have little to no resemblance to the cells from which they originated (in this case pancreatic cells). Tumors classified as G1 or G2 are considered low grade tumors with well and moderately differentiated cells, respectively. Tumors classified as G3 or G4 are considered high grade tumors with poorly or undifferentiated cells, respectively. Many factors are considered in determining tumor grade, including the structure and growth pattern of the cells. Tumor grade is determined by a pathologist via biopsy of the tumor. Higher degrees of cancer cell abnormality are associated with a poorer disease prognosis; in fact, high tumor grade is an independent predictor of survival. The study conducted by Lim et al. referred to above showed that patients with poorly differentiated (G3), or higher grade, tumors of the pancreas had median overall survival of 22.8 months less than patients with well differentiated (G1), or lower grade, tumors.

Ca 19-9 markers: refers to the post-operative concentration of the tumor marker carbohydrate antigen 19-9. The concentration of Ca 19-9 markers is associated with significant risk of early, distant metastasis. A study conducted by Kinsella et al. published in *American Journal of Clinical Oncology* in 2008 reported that pancreatic cancer patients with high post-operative Ca 19-9 levels, defined as greater than 70 units per milliliter, had a median overall survival 16.8 month less than patients with Ca 19-9 marker levels lower than 70 units per milliliter.

Our Phase 2 clinical trial did not compare the outcomes of patients who received HyperAcute Pancreas plus the standard-of-care treatment regimen to the standard-of-care alone. Therefore, we believe it is important to evaluate the patient characteristics and clinical results of NLG-0205 relative to those of prior clinical trials in surgically-resected pancreatic cancer patients.

NLG-0205 has met its primary objective for one-year disease-free survival. NLG-0205 one-year disease free survival of 63% and one-year overall survival of 86% compares favorably to the 221 patients in RTOG 97-04 receiving gemcitabine plus 5-FU based chemoradiotherapy, who had less than 50% one-year disease-free survival and 69% one-year overall survival. The NLG-0205 data demonstrates a statistically significant improvement in disease-free survival at one year for the high dose (300 million cell) arm of the study compared to the lower dose (100 million cell) arm of the same study. This is particularly noteworthy given that the NLG-0205 high dose cohort patients are either equal to or worse than the low dose cohort in every major comparable prognostic indicator.

Study	Nodal Status (% N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (³ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival at 1 Year
NLG-0205 (70 patients) Gemcitabine + 5-FU + Radiation + HyperAcute Pancreas	**81%**	**90%***	**83%**	**36%***	**17%***	**14.3**	**86%**
NLG-0205 Low Dose (44 patients)	**80%**	**90%***	**77%**	**34%***	**16%***	**12.9(1)**	**80%**
NLG-0205 High Dose (26 Patients)	**85%**	**91%***	**92%**	**40%***	**19%***	**15.3(1)**	**96%**

(1) Calculated as of September 1, 2011.

* Calculation excludes unknowns.

U.S.-based comparator studies

In terms of historical comparisons between NLG-0205 and other resectable pancreatic cancer trials with curative intent, we believe RTOG 97-04 represents the most appropriate comparator study. This clinical trial enrolled 538 patients at 164 U.S. and Canadian institutions from July 1998 to July 2002 with follow-up through August 2006. The objective of RTOG 97-04 was to determine if the addition of gemcitabine to adjuvant 5-FU chemoradiation would improve survival for patients with resected pancreatic adenocarcinoma. In their primary analysis of a 451 patient sub-population, 221 of which received

gemcitabine, the RTOG 97-04 investigators determined that the addition of gemcitabine to adjuvant 5-FU-based chemoradiation was associated with a survival benefit for patients with resected pancreatic cancer, although this benefit was not statistically significant. Based on the subpopulation analysis of this study, we believe that this study demonstrated limited benefit. The results of RTOG 97-04 were presented at the 2006 American Society of Clinical Oncologists, or ASCO, annual meeting and published in *JAMA* in March 2008.

Study	Nodal Status (%N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (³ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival Median (Months)	Overall Survival at 1 Year
RTOG 97-04 2008(1) Treatment Arm: Gemcitabine + 5FU + Radiation (221 patients)	**68%**	**Not reported**	**81%**	**32%***	**14%(2)**	**11.4(3)**	**20.5(3)**	**69%**
NLG-0205 Gemcitabine + 5-FU + Radiation + HyperAcute Pancreas (70 patients)	**81%**	**90%***	**83%**	**36%***	**17%***	**14.3**	**—(4)**	**86%**

(1) Regine et al., *JAMA* 2008; 299(9): 1019-1026.

(2) Includes only the 124 patients who tested positive for the Lewis antigen (patients who test negative for the antigen do not express Ca 19-9).

(3) Regine et al. study in *JAMA* only reports overall survival and disease-free survival for patients with pancreatic head tumors. The median overall survival of patients in the standard-of-care treatment arm of RTOG 97-04 is 18.8 months.

(4) Not calculable as of September 1, 2011.

* Calculation excludes unknowns.

RTOG 97-04 baseline patient characteristics are the most similar to NLG-0205 baseline patient characteristics; both studies enrolled patients primarily at major medical centers in the United States, and NLG-0205 incorporates the addition of HyperAcute Pancreas to a chemoradiotherapy protocol highly similar to that used in RTOG 97-04.

Since comparisons between specific studies can have distinct limitations, other approaches have been created to evaluate the likely impact of therapies on overall survival. To expand prognostication beyond the AJCC system, researchers have developed statistical tools such as multi-component nomograms that incorporate large numbers of independent variables, including adjuvant therapy, to permit calculations of likely outcomes for post-surgical pancreatic cancer patients. One such nomogram has been developed for surgically resected Stage I/II patients based on the interaction of multiple prognostic indicators identified at Memorial Sloan Kettering Cancer Center over a 17-year period. We have evaluated our entire patient population using this nomogram. The nomogram analysis of the NLG-0205 patients predicted a 63% overall survival at one year following standard therapy. This is in contrast to one-year survival rates of 86% for all patients and 96% for high dose patients in our clinical trial. We believe this represents an additional demonstration that the survival data from NLG-0205 is consistent with an improvement in survival arising from the use of HyperAcute Pancreas in the adjuvant setting.

European studies

It is important to recognize differences in patient selection that may exist between trials due to differences in surgical approaches between United States and Europe. For example, according to Picozzi, in *Business Briefing: US Gastroenterology Review* in 2005, less than 3% of Stage I/II pancreatic cancer patients receive surgery in the United Kingdom. Gebhardt, in *Langenbeck's Archives of Surgery* (2000) 385:14-20, notes that the surgery frequency is approximately 20% in the United States. The major European studies can be summarized as follows:

ESPAC-1: This clinical trial initially recruited 541 patients at 53 hospitals in 11 European countries from February 1994 to June 2000. The final data analysis published in March 2004 was based on an

evaluation of 289 patients. The objective of ESPAC-1 was to evaluate potential survival benefits of post-surgical adjuvant therapy: chemotherapy, chemoradiotherapy, chemoradiotherapy followed by chemotherapy and no-treatment/observation. The investigators in this clinical trial concluded that adjuvant chemotherapy with 5-FU has a significant survival benefit in patients with resected pancreatic cancer while chemoradiotherapy may have had a negative impact on survival. We believe ESPAC-1 lacked adequate statistical power to draw any meaningful conclusions regarding superiority of any of the treatment arms. Results of ESPAC-1 were published in the *New England Journal of Medicine* in March 2004.

CONKO-001: This clinical trial enrolled a total of 368 patients at 88 academic and community-based oncology centers in Germany and Austria from July 1998 to December 2004. The objective of CONKO-001 was to test the hypothesis that adjuvant chemotherapy with gemcitabine administered after complete resection of pancreatic cancer improves disease-free survival by six months or more relative to best supportive care. In their analysis of 354 eligible patients, the CONKO-001 investigators concluded that adjuvant gemcitabine delayed the development of recurrent disease compared to observation alone. However, a statistically significant benefit in overall survival was not observed. CONKO-001 results were published in *JAMA* in January 2007.

ESPAC-3: This clinical trial enrolled a total of 1,088 patients at 159 pancreatic cancer centers in Europe, Australasia, Japan, and Canada from July 2000 to January 2007. The objective of ESPAC-3 was to determine whether treatment with 5-FU/FA or gemcitabine is superior in terms of overall survival as adjuvant treatment following resection of pancreatic cancer. ESPAC-3 is the largest adjuvant trial conducted in pancreatic ductal adenocarcinoma. However, the treatment regimens in ESPAC-3 lacked standardization in terms of dosing and schedule and the investigators elected not to include an observation arm in this study following the results of ESPAC-1, which prevented an analysis of baseline patient risk for enrollees in this trial. We believe these elements of the ESPAC-3 trial design limit the applicability of its conclusions to clinical practice. The results of ESPAC-3 were presented at the ASCO 2009 annual meeting and published in *JAMA* in September 2010.

Study	Nodal Status (% N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (³ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival Median (Months)	Overall Survival at 1 Year
ESPAC-1 (289 patients) 2004(1) Treatment Arm: 5-FU (147 patients)	**52%***	**18%***	**Not reported**	**18%***	**Not reported**	**Not reported**	**20.1**	**67%**
CONKO-001 (354 patients) 2007(2) Treatment Arm: Gemzar (179 patients)	**71%**	**Not reported**	**86%**	**36%***	**0%**	**13.4**	**22.1**	**73%**
ESPAC-3 (1088 patients) 2010(3) Treatment Arm: Gemcitabine (537 patients)	**73%**	**43%**	**64%**	**24%**	**Not reported(4)**	**14.3**	**23.6**	**80%**

(1) Neoptolemos et al., *New England Journal of Medicine* 2004; 350:1200-1210.

(2) Oettle et al., *JAMA* 2007; 297(3): 267-277.

(3) Neoptolemos et al., *JAMA* 2010; 304(10):1073-1081.

(4) Postoperative levels of Ca 19-9 were recorded in 373 of the 537 gemcitabine treatment arm patients. Only patients with Ca 19-9 levels in the interquartile (25th to 75th percentile) range of recorded events were reported, with a reported range of 9 to 62 units per milliliter and a median of 22 units per milliliter.

* Calculation excludes unknowns.

The baseline characteristics for the NLG-0205 clinical trial are notably different compared to the three most commonly cited European trials. These differences in study populations are noteworthy:

- The ESPAC-1 and ESPAC-3 studies had substantially fewer patients with lymph node spread (NLG-0205 81% vs. 52-73%), local invasion (NLG-0205 90% vs. 18-43%) and high grade tumors (NLG-0205 35% vs. 18-24%) and did not report patients with elevated Ca 19-9 levels.

- The CONKO-001 trial specified active exclusion of patients with elevated Ca 19-9 levels, the tumor marker used to predict the likelihood of recurrence in patients following surgical resection of the primary pancreatic tumor. Consequently, NLG-0205 had 17% of patients with elevated Ca 19-9 vs. none for the CONKO-001 study.

Furthermore, as these studies do not follow harmonized or standardized study regimens, generating meaningful conclusions about specific therapeutic regimens is difficult. These differences in surgical practice, study patient selection, and study therapeutic regimens are so different from the NLG-0205 protocol, we believe it is unlikely that meaningful comparisons can be made; however, the data is at least illustrative of the differences in medical practice for this disease in the United States relative to that of the European and international oncology community.

Our HyperAcute Lung Cancer Immunotherapy Product Candidate

Our HyperAcute Lung product candidate is being studied in a combined Phase 1/2 clinical trial that is fully enrolled with 54 patients for the treatment of refractory, recurrent or metastatic nonresectable NSCLC. This trial is being conducted at the NCI. HyperAcute Lung consists of a group of three separate allogeneic lung tumor cell lines that were modified to express the gene that makes a-GT. These three cell lines are representative of the three major types of NSCLC. Each of the modified cell lines is grown in large cultures, harvested, irradiated, and packaged. Approximately 100 million cells of each HyperAcute Lung cell line are given by intradermal injection with each treatment.

Market Opportunity

According to the American Cancer Society, lung cancer is the leading cause of cancer-related death in the United States. The NCI estimates that over 157,000 Americans will die of the disease in 2010, accounting for approximately 28% of all cancer deaths. Lung cancer is most often diagnosed at advanced stages when it is difficult to treat. According to the American Cancer Society, about 85% to 90% of lung cancers are classified as NSCLC. The remaining lung cancers are classified as small cell lung cancer. The American Cancer Society also reports that about 80% of NSCLC cases are detected when they have progressed to stages III or IV. A study published in the *Journal of Clinical Oncology* in 2004 states that the current expected overall survival for a nonresectable stage IIIB or IV NSCLC patient who has failed first line treatment is approximately eight months.

Clinical Trials

Phase 1/2 Clinical Trial

HyperAcute Lung is currently in a Phase 1/2, single-arm, open-label clinical trial that is fully enrolled with 54 patients at the NCI. This clinical trial is for patients with refractory, recurrent or metastatic NSCLC. Its primary endpoint is to assess tumor response rate after administration of HyperAcute Lung, and the secondary endpoint is to assess overall survival. For the Phase 1 portion of this clinical trial, a positive response included stable disease for 16 weeks in patients who had enrolled after having previously shown progressive disease. A total of 17 patients in the Phase 1 portion and 37 patients in the Phase 2 portion were injected with HyperAcute Lung. Of the 37 patients in the Phase 2 portion, only 28 were evaluated for clinical response. In the Phase 1 portion, four cohorts of patients each received injections of 3 million, 10 million, 30 million, or 100 million cells every four weeks for four doses, and one cohort of

three patients received an initial dose of 500 million cells, followed by injections of 300 million cells every two weeks for up to seven doses. In the Phase 2 portion, the 28 patients evaluated received injections of 300 million cells every two weeks for up to eight doses.

The interim results of our Phase 1/2 clinical trial for HyperAcute Lung, based on an interim analysis of 45 patients, were encouraging. As of December 9, 2010, the interim results for the 28 patients evaluated in the Phase 2 clinical trial group showed a median progression-free survival of 14.6 weeks, median overall survival of 11.3 months, and a one-year survival rate of 46%. Median overall survival data from the Phase 2 clinical trial group was better than the Phase 1 clinical trial group (11.3 versus 7.6 months), a comparison that would be consistent with study drug dose dependency. Overall survival of patients in our Phase 1/2 clinical trial trended with the persistent elevation of anti-a-Gal immunoglobulin (IgG) antibodies. Some patients with longer overall survival demonstrated increased secretion of interleukin-5 (IL-5) and gamma-interferon (IFNg).

Prior Phase 3 studies suggest that in the refractory, recurrent or metastatic NSCLC setting (second line therapy), the median overall survival of patients receiving best supportive care was 4.6 months and the median overall survival of patients receiving pemetrexed or docetaxel (Taxotere) therapy was approximately eight months. Given the favorable safety profile of HyperAcute Lung and 11.3 month median overall survival observed in the Phase 2 study, HyperAcute Lung compares favorably to current standard-of-care cytotoxic chemotherapy. We are currently evaluating alternative designs for a Phase 2B/3 clinical trial in NSCLC with an adaptive design, which we plan to initiate in the first half of 2012 and on which we plan to complete the first interim analysis in 2013. The following table shows comparative results for second-line treatment in advanced NSCLC with pemetrexed, docetaxel and HyperAcute Lung.

Treatment Options and Clinical Outcomes in 2nd Line Advanced Stage NSCLC

Therapy	Overall Survival (Months)	12 Month Survival	Serious Adverse Events (CTC Grade 3 or 4) Attributed to Therapy			
			Nausea	Fatigue	Anemia	Neutropenia
Best supportive care(1)	4.6	11%	—	—	—	—
Docetaxel(1)	7.5	37%	1.8%	5.4%	4.3%	40.2%
Pemetrexed(2)	8.3	30%	2.6%	5.3%	4.2%	5.3%
HyperAcute Lung(3)	11.3	46%	0%	0%	0%	0%

(1) Prospective Randomized Trial of Docetaxel versus Best Supportive Care in Patients with Non-Small-Cell Lung Cancer Previously Treated With Platinum-Based Chemotherapy. Shepherd et al., *Journal of Clinical Oncology*, Volume 18, No. 10 (May), 2000: pp 2095-2103

(2) Randomized Phase III Trial of Pemetrexed Versus Docetaxel in Patients with Non-Small-Cell Lung Cancer Previously Treated with Chemotherapy. Hanna et al., *Journal of Clinical Oncology* 2004 May 1; 22(9):1589-97

(3) Data from NLG-0101 clinical trial Patients 18-45

The Phase 1 portion of our Phase 1/2 clinical trial for our HyperAcute Lung demonstrated a favorable safety profile, with no dose limiting toxicities at any of the five escalating dose levels. There have been no reported CTC grade four adverse events attributed to HyperAcute Lung and only one serious adverse event (CTC grade three lymphopenia) characterized by investigators as possibly or probably attributable to HyperAcute Lung. The most common treatment-related adverse reactions (reported by at least 5% of patients) for HyperAcute Lung were injection site reaction (92%), induration (56%), fatigue (25%), urticaria (12%), anemia (7%), pruritus (7%), lymphopenia (7%), elevated serum amylase (5%), edema (5%), skin pain (5%) and dyspnea (5%). The clinical trial involved a dose escalation from approximately three million up to 300 million cells in repeat dosing. Only a single dose escalation has been required by the FDA in all subsequent clinical trials of our other HyperAcute product candidates conducted to date.

Our HyperAcute Melanoma Immunotherapy Product Candidate

Our HyperAcute Melanoma product candidate is being studied in an investigator-initiated Phase 2 clinical trial in 25 patients with advanced melanoma. In this trial, HyperAcute Melanoma is being administered in combination with an eight-week course of PEG-Intron, a man-made immune modulator that has been tested for the treatment of melanoma. HyperAcute Melanoma consists of a group of three allogeneic melanoma tumor cell lines that were modified to express the gene that makes a-GT. These three cell lines each possess collections of known melanoma antigens so that the immune response they stimulate will provide broad coverage. Each of the modified cell lines is grown separately in large cultures, harvested, irradiated and packaged. Approximately 50 million cells of each HyperAcute Melanoma cell line are given by intradermal injection with each treatment.

Market Opportunity

Melanoma is an often lethal form of skin cancer. If it is not recognized and treated early, the cancer can advance and spread to other parts of the body, where it becomes hard to treat and can be fatal. While it is not the most common of the skin cancers, it causes the most deaths. The American Cancer Society estimates that in 2009 there were 8,650 deaths from melanoma in the United States and there will be approximately 68,000 new cases of melanoma in the United States in 2010.

Phase 2 Clinical Trial

We provided HyperAcute Melanoma product to, and are collaborating with, Dr. Adam Riker at the Ochsner Cancer Institute in New Orleans, Louisiana, in support of a Phase 2 investigator-initiated clinical trial studying HyperAcute Melanoma in combination with an eight week course of PEG-Intron for patients with advanced melanoma. The trial reached its 25-patient enrollment goal in September 2010. The treatment consists of 12 weekly injections of HyperAcute Melanoma with PEG-Intron being co-administered in weeks five through 12. This is the first time that one of our HyperAcute immunotherapies has been combined with another approved immunotherapy, in this case PEG-Intron. The primary objective of this clinical trial is to conduct correlative scientific studies of patient tumor and peripheral blood samples to determine the mechanism of any observed anti-tumor effect involving the innate and cell-mediated host immune response to HyperAcute immunotherapy alone and combined with PEG-Intron. Although the number of patients in this clinical trial is modest, the results to date are encouraging. Among 10 patients with Stage IV melanoma and non-visceral metastases, there were three (30%) responders, two complete responders and one with stable disease.

As of September 8, 2011, vitiligo was observed in four out of 25 (16%) patients. Vitiligo is an autoimmune condition in which the patient's immune system attacks melanoctyes, the cells responsible for skin pigmentation and potential melanoma cancer cells. Two prior clinical trials of immunotherapies conducted by others suggest that the development of vitiligo was correlated with a favorable response to therapy in melanoma patients. All patients evaluated developed autoimmune antibodies. Other than vitiligo, no other clinically apparent autoimmune disorder has been reported in any patient to date. These observations suggest an immunological response to the HyperAcute Melanoma. HyperAcute Melanoma has demonstrated good tolerability and a favorable safety profile, with no systemic, drug-related serious adverse events characterized by the investigators as possibly or probably attributable to our product candidate. The most common non-serious adverse events reported were injection site reactions, induration, diarrhea and nausea. The small scale of this clinical trial and the fact that it was performed at a single institution limit our ability to draw significant conclusions from the data; however, durable complete responses to metastatic disease in this setting are rarely seen.

We currently are developing new clinical trial designs to evaluate the efficacy of HyperAcute Melanoma either as a stand-alone or combination therapy in these new settings. Specifically, in the Phase 2 clinical trial of our HyperAcute Melanoma product candidate, we employed a weekly dose of 150 million

cells for 12 weeks during the course of the treatment. After enrollment was completed in the Phase 2 clinical trial of HyperAcute Melanoma, data from our Phase 2 clinical trial of HyperAcute Pancreas showed a statistically significant improvement in disease-free survival when comparing patients receiving doses of 100 million cells to those receiving doses of 300 million cells. Our Phase 3 HyperAcute Pancreas clinical trial protocol was amended to administer 18 injections of 300 million cells to patients over a 12 month period. We also intend to employ a 12 month treatment schedule employing the 300 million cell dosing level in our next Phase 2B HyperAcute Melanoma clinical trial, which we plan to initiate in 2012. This will represent a three-fold increase in total dose compared to the initial Phase 2 HyperAcute Melanoma clinical trial.

Our Other HyperAcute Cancer Immunotherapy Product Candidates and Indications

We believe we have developed a process to efficiently discover and develop new tumor-specific HyperAcute immunotherapies for other solid tumor types. We have initiated clinical development for our HyperAcute Prostate and HyperAcute Breast product candidates and are developing our HyperAcute immunotherapy technology for other indications.

Our HyperAcute Prostate Cancer Immunotherapy Product Candidate

Prostate cancer is one of the most common forms of cancer affecting men. According to the American Cancer Society, there will be over 217,000 patients diagnosed with prostate cancer in the United States in 2010. Increased screening over the past few decades has enabled physicians to detect prostate cancer in its early, more treatable stages. Nonetheless, while overall five-year survival rates for cases of prostate cancer approach 100%, the outlook for advanced, metastasized cases is poor with five-year survival rate of 31%, according to the American Cancer Society.

We have completed an open-label, single-center Phase 1 clinical trial for our HyperAcute Prostate product candidate. This clinical trial enrolled eight patients with hormone refractory prostate cancer that had recurred or no longer responded to standard treatment. Study participants received 12 bi-weekly intradermal injections of HyperAcute Prostate, which consists of two separate allogeneic prostate cancer cell lines that were selected based on antigen profiles and modified to express the gene that makes a-GT. The primary endpoint for this clinical trial was safety and efficacy of administration. We successfully completed this clinical trial in August 2008. We observed no dose-limiting toxicities and only one serious adverse event (CTC grade three anemia) was reported by the investigator as possibly attributable to HyperAcute Prostate. Median survival was 25.1 months (range 5-60 months) with one treated patient remaining alive at 60 months with stable Prostate Specific Antigen and unchanged bone metastasis since 2007. Although we currently do not have an active IND for this indication due to resource constraints, we believe HyperAcute Prostate could provide a valuable treatment alternative for many prostate cancer patients.

Our HyperAcute Breast Cancer Immunotherapy Product Candidate

According to the American Cancer Society, carcinoma of the breast is the second leading cause of cancer death in women in the United States with over 207,000 new cases and 39,800 deaths estimated in 2010. Increased access to improved screening methods has had a major impact on reducing deaths from this disease; however, despite these interventions, patients continue to present with nodal or metastatic lesions that carry poor prognoses.

We initiated an open-label, single-center Phase 1 clinical trial for our HyperAcute Breast product candidate. Three patients were enrolled in this clinical trial. Due to resource constraints, the clinical trial was suspended.

HyperAcute Breast consists of two allogeneic breast cancer cell lines genetically modified to express the gene that makes a-GT. The cell lines selected for inclusion in this drug represent both estrogen

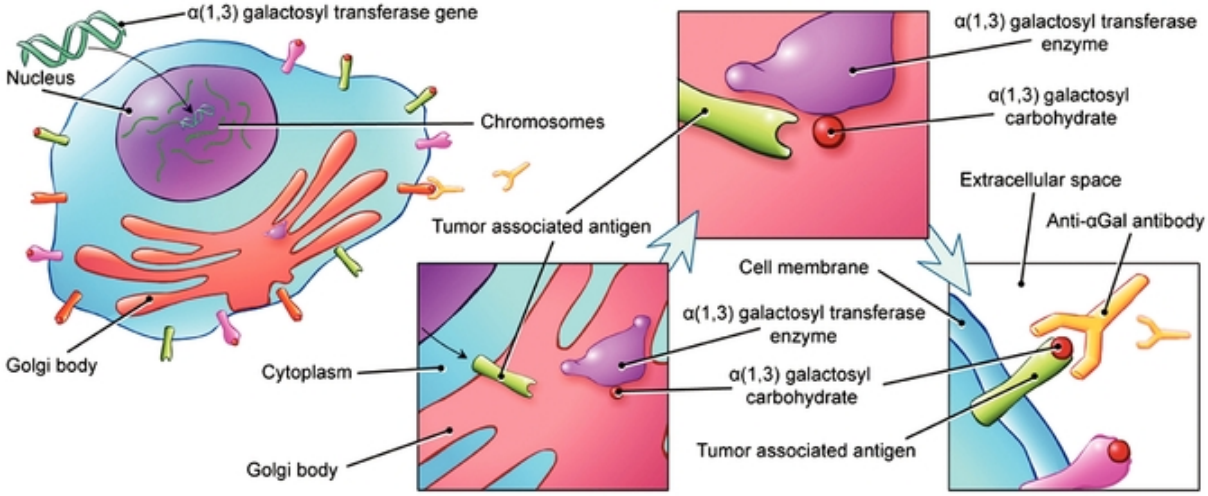
receptor positive and estrogen receptor negative examples of disease. The cell lines of the drug are manufactured with growth nutrient in media by concentrating, irradiating and compounding in a cryopreservative solution. Although we currently do not have an active IND for this indication, we believe HyperAcute Breast could provide a valuable treatment alternative for many breast cancer patients.

Our HyperAcute Cancer Immunotherapy Technology

Compared to prior immunotherapy approaches, our proprietary HyperAcute immunotherapy technology offers several distinct advantages including:

- a robust innate immune response that harnesses the human body's naturally protective and rapid immune reaction to the a-Gal carbohydrate to fight cancer;
- a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- an allogeneic, or non-patient specific, approach, in which we manufacture products from genetically modified, allogeneic cells from previously established cell lines, which permits an easier scale-up of the manufacturing process compared to an autologous, or patient specific, approach involving a patient's own cells.

We believe our HyperAcute immunotherapies operate by exploiting a natural barrier present in humans that protects against infections being transmitted from other mammals. This barrier is related to the enzyme a-GT, which is expressed in the cells of lower mammals but not present in human or other Old World primate cells. The presence of this enzyme results in the expression of a non-human form of carbohydrate called a-Gal on the surface of affected cells. Introducing a-Gal expressing cells to the human or primate immune system activates an immune response from antibodies against a-Gal. Antibodies directed against the a-Gal epitope are potentially the most abundant antibody in humans and represent approximately 1% of circulating human antibodies.



The figure above represents our HyperAcute Immunotherapy process. The a-GT gene is inserted into the chromosome within the cancer cell. The gene then yields a protein called a-GT enzyme which is located within the Golgi body of the cell where macromolecules, such as proteins and lipids, are processed and packaged. Proteins, like the illustrated tumor associated antigen, that are processed through the Golgi, are tagged with a-Gal carbohydrate and placed on the surface of the cell. The a-Gal carbohydrate located on the surface of the tumor associated antigen is now targeted by anti-aGal antibodies causing the hyperacute immune response to be initiated.

HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes a-Gal epitopes. This exposure to a-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which a-Gal is present by activating complement, an important component of the immune system that is capable of cell destruction. After destruction, we believe the resulting cellular fragments bound by anti a-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to tumor-associated antigens common to both the immunotherapy and the patient's tumor cells.

In the early 1990s, the NCI conducted experiments in brain cancer patients involving the implantation of mouse cells that had been engineered to produce a virus to genetically attack cancer cells in the brains of cancer patients. Promising results in these clinical trials led our founder and others to attempt a similar experiment in ovarian cancer patients in 1995. However after that therapy, genetic testing of biopsies from these patients demonstrated that this gene transfer approach was ineffective. Nonetheless, the clinical trial suggested clinical benefit in four of nine evaluated patients. During the clinical trial, it was observed that the ovarian cancer patients had a vigorous immune response to the infusion of the mouse cells, characterized by fever and abdominal pain. Further study and comparison to the work of transplant scientists who were attempting to understand the mechanism of xenotransplant rejection (the rejection of tissues transplanted from a different species) identified a carbohydrate on the surface of mouse cells known as a-Gal that may have triggered the ovarian cancer patient's immune systems to mount an attack on the mouse cells. This immune response was led by existing anti-a-Gal antibodies in a manner very similar to "hyperacute rejection," the rapid destruction of tissues transplanted from lower animals.

Evolutionary biologists believe that the ancestors of humans lost the functional gene to produce a-Gal about 25 million years ago. Because the cells or pathogens originating in nonhuman species (for example domestic pets) contain a-Gal, they are rapidly destroyed by anti- a-Gal antibodies present in substantially all humans. This process likely helps humans to defeat infection from other species. Humans develop these antibodies as a result of constant exposure to a-Gal from the beneficial bacteria normally found in the digestive system and through exposure to cells carrying a-Gal on the meat in the diets of humans. We believe the cancer cells in the ovarian cancer patients were immunologically destroyed as a result of being adjacent to the mouse cells carrying the a-Gal gene, and we term this the "hyperacute" response.

In the case of a HyperAcute cancer immunotherapy, this process results in immune cells that are educated to attack a patient's own cancer cells by virtue of the antigens which the immunotherapy and these tumor cells share and by a more generalized activation of the immune system. Our scientists have shown in mouse models of cancer that the immune system responds after a HyperAcute injection by attacking all similar cancer cells, including those that have no a-Gal carbohydrate. In the case of a HyperAcute viral immunotherapy, because of the high concentration of anti-a-Gal antibodies, there is a clearance and processing of immunotherapy containing the a-Gal epitope, significantly boosting immune responses to some target pathogens.

HyperAcute immunotherapies are designed to break tolerance and enable longer duration of anti-tumor effect. We believe that our HyperAcute immunotherapy technology induces a unique combination of advantageous immunologic effects. Our current understanding of the mechanism of HyperAcute immunotherapy includes the following concepts, although our understanding of this technology continues to evolve. The immune response is triggered by formation of immunocomplexes between the a-Gal-containing cells or viral vaccines and pre-existing, naturally occurring, high-titer antibodies to a-Gal that are present in every patient screened by us to date. Formation of immunocomplexes by complement-fixing anti-Gal antibodies activates complement-mediated cell lysis, which generates immune system "danger signals" that elicit activation and recruitment of antigen presenting cells, or APCs, of multiple lineages. The anti-a-Gal-dependent generation of immune responses involves activation of multiple types of immune system effector cells, such as dendritic cells, macrophages and natural killer (NK) cells. These cells which have taken up the lysed or fragmented HyperAcute immunotherapy cells have responses against multiple tumor targets and act by different modes of action,

both cellular and antibody mediated. The process of FcgR-mediated phagocytosis, whereby antibodies bind to the immunotherapy cells and form a connection to a specific region that facilitates uptake by APCs, results in activation of certain immune cells called cytotoxic CD8+ T-cells and CD4+ helper T-cells, as well as stimulation of tumor antigen-specific B-cells. Hyperacute immunotherapy has produced long-term complete responses in an animal model of metastatic disease. Further study in human cancer patients will need to be correlated with observations in preclinical models.

Our IDO Pathway Inhibitor Product Candidate

We are developing d-1-methyltryptophan, or D-1MT, a small-molecule, orally bioavailable product candidate based on our proprietary IDO pathway inhibitor technology. Preclinical experiments have demonstrated a strong, synergistic anti-tumor effect without increased toxicity when D-1MT was administered in combination with a number of currently available chemotherapeutic agents. D-1MT is currently being evaluated for the treatment of a broad range of solid tumors in chemotherapeutic and immunotherapeutic combinations in two Phase 1B/2 clinical trials.

Clinical Trials

Phase 1B/2 Clinical Trials

We currently have two Phase 1B/2 clinical trials enrolling patients to evaluate D-1MT in combination with other approved therapies. The first clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with an Ad-p53 autologous dendritic cell vaccine for solid malignancies with p53 mutations, such as lung, breast and colon cancers. As of August 12, 2011, 19 patients have been enrolled in the Phase 1B dose escalation portion of this clinical trial. The Phase 2 clinical trial portion of the D-1MT/Ad-p53 study will expand primarily to enroll patients with metastatic breast cancer. The second clinical trial has primary endpoints that assess safety and efficacy of D-1MT in combination with Taxotere for patients with advanced stage solid tumors for which Taxotere is the standard-of-care, such as metastatic breast, prostate, ovarian and lung cancers. As of July 7, 2011, five patients have been enrolled in the Phase 1B dose escalation portion of this clinical trial. The Phase 2 clinical trial portion of the D-1MT/Taxotere study will expand primarily to enroll patients with metastatic breast cancer. We believe D-1MT has the potential to have a synergistic therapeutic effect in combination with Ad-p53 or Taxotere without adding systemic safety complications. The clinical trials are being co-sponsored by the NCI's Division of Cancer Treatment and Diagnosis under a Cooperative Research and Development Agreement and letter of intent and are taking place at the Moffitt Cancer and Research Institute in Tampa, Florida.

According to the American Cancer Society, in the United States, breast cancer is the most common cancer among women, other than skin cancer. According to the American Cancer Society, there are projected to be approximately 207,000 new cases in 2010, and approximately 39,800 patients are expected to die of the disease. The disease comes in different forms depending on whether the tumor is driven by signaling through the estrogen receptor (approximately 70% of patients), the HER2/neu receptor (approximately 15-20% of patients), or neither. In the early stages, breast cancer may have no symptoms and can be detected only through mammography screening. During the later phases, symptoms may include tenderness, swelling, lumps, and skin irritation. Treatment of breast cancer typically includes surgery to remove tumors and lymph nodes. Usually a combination of radiation, chemotherapy or hormonal therapy is used post-surgery. Although the use of mammography screening has driven a trend toward earlier-stage diagnosis and decreased mortality, approximately 5% of new breast cancer cases will be Stage IV at the time of diagnosis in 2010. Metastatic breast cancer can be treated with a variety of monotherapy or combination drug regimens. According to the NCI, the overall five-year survival rate for breast cancer is 89%, but the outlook for advanced metastasized cases is poor with five-year survival rates of 23.4%.

Phase 1 Clinical Trials

We are nearing completion of two Phase 1 clinical trials of D-1MT as a single agent. These Phase 1 clinical trials were open to all tumor types and enrolled patients with a wide variety of cancers. The principal goal of these trials was to demonstrate that patients can tolerate the drug and that increasing quantities of the drug can be administered without inducing toxicity that would prevent the attainment of efficacy. We have observed autoimmune hypophysitis in a small subset of patients previously sensitized to immunotherapy (ipilimumab) and in one immunotherapy-naive patient receiving high dose D-1MT. Autoimmune hypophysitis is a disease that most commonly occurs with chronic inflammation of the pituitary gland and may be characterized by diminished production of one or more hormones by the pituitary gland. Autoimmune hypophysitis can be successfully managed by hormone replacement therapy during acute or chronic phases.

We have had few serious adverse events with D-1MT in the Phase 1 studies, limited primarily to the hypophysitis, and are proceeding with Phase 1B/2 studies. We have observed one reported CTC grade four (cerebrovascular ischemia) and two reported CTC grade three (lymphopenia) serious adverse events characterized by the investigators possibly, probably or definitely attributable to D-1MT in the clinical trial combining D-1MT with Ad-p53. There have been no reported serious adverse events characterized by the investigators as attributable to D-1MT in the clinical trial combining D-1MT with Taxotere.

Our IDO Pathway Inhibitor Technology

IDO pathway inhibitors, including D-1MT, represent a potential breakthrough approach to cancer therapy using small-molecule, anti-toleragenic product candidates intended to combat the mechanisms by which tumors evade immune-mediated destruction. IDO is an enzyme that regulates immune response by suppressing T-cell function and creating local tumor immune escape. Recent studies have demonstrated that IDO is overexpressed in many cancers, within both tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor draining lymph nodes whereby IDO promotes peripheral tolerance to TAAs. When hijacked by developing cancers in this manner, IDO may facilitate the survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system as foreign.

We believe that immune system failure is a fundamental reason for the inability of the human body to successfully fight cancer cells. Research into the inability of the immune system to respond to cancerous tumors indicates that tumors can induce the human immune system to tolerate the existence of the tumor. This immune tolerance and suppression represents a major barrier to successful treatment of cancer and is a significant target for new therapeutics.

Scientific understanding of the process leading to immune tolerance is in its early stages. We believe IDO is part of a system that may be used by some tumors as a mechanism to evade the immune system. IDO is an enzyme that regulates immune response by suppressing effector T-cell function by breaking down the essential amino acid tryptophan. Expression of IDO, either directly by tumors or by dendritic cells in tumor-draining lymph nodes, has been shown in animal studies to induce immune tolerance to tumors, and inhibition of IDO has been shown in these studies to prevent this induction of tolerance. IDO is rarely expressed by the majority of normal tissues, but it is overexpressed in many types of human tumors.

Cytotoxic chemotherapy places substantial stress on established, tumor-induced tolerance. Several factors can potentially contribute to this result: (1) dying tumors cells release waves of TAAs for processing and presentation, (2) many chemotherapeutic regimens induce a period of transient lymphopenia and homeostatic recovery during which T-cells may become more susceptible to breaking tolerance, and (3) certain regimens can transiently deplete or inactivate tumor-protective T-regulatory cells. Despite producing these challenges to tolerance, most chemotherapeutic agents do not appear to trigger a protective immune response against established tumors. This shortcoming of traditional chemotherapy has

been attributed, in part, to the ability of tumors to rapidly reestablish tolerance following each cycle of chemotherapy. We believe a potential mechanism underlying the failed opportunity is IDO expression by APCs in tumor-draining lymph nodes, which are thereby converted to an immunosuppressive and tolerance-inducing milieu. Preclinical data have demonstrated that IDO pathway inhibitors have anti-tumor effects in combination with a number of radiotherapy, chemotherapeutic drugs or other immunotherapy drug candidates and may work better together than either type of treatment alone.

The ability to acutely eliminate the protective IDO mechanism by administering IDO pathway inhibitor drugs, such as D-1MT, may provide a therapeutic window in which to break tolerance in tumors and reverse the inhibition of immune cells. Additionally, we believe that once immune cells are restored to normal function, they can assist in the rejection of tumors.

We believe our IDO pathway inhibitor technology has the following potential advantages in combating cancers:

- *Potential to break immune tolerance.* The immune tolerance to cancerous cells represents a key barrier to the treatment of cancer. To date, few available therapies have addressed the immune escape mechanisms of cancer. We believe inhibition of the IDO pathway has the potential to break a key immune escape mechanism of cancer cells and significantly enhance patient outcomes.
- *Tolerability.* In early-stage clinical development, we have observed an encouraging safety profile. We believe inhibition of the IDO pathway will selectively enhance the immune response against cancer cells given the limited expression of IDO in normal cells.
- *Oral bioavailability.* Unlike many cancer therapies which require intravenous administration, our D-1MT IDO pathway inhibitor is orally bioavailable, a significant advantage in ease of administration for patients and physicians.
- *Synergy with existing cancer therapies.* Inhibiting the IDO pathway in conjunction with chemotherapy has the potential to enhance the therapeutic effect of chemotherapy by delaying or disrupting the reacquisition of immune tolerance to tumor antigens during the period following chemotherapy. We believe our IDO pathway inhibitors could also have therapeutic synergy with targeted therapeutics, radiation and immunotherapy. The safety profile in humans is conducive to exploring combination therapy and the available animal data does not indicate significant additive or synergistic toxicities with many common oncology therapies.

BioProtection Systems Corporation

BioProtection Systems Corporation, or BPS, was founded by the Company as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens likely to be targeted to the human population through acts of bioterrorism. In 2010, we owned a majority of BPS's common stock on an as-converted basis. On January 7, 2011, we acquired the minority interest in BPS and BPS became a wholly-owned subsidiary of the Company.

BPS is based upon three core technologies, each of which can be leveraged into the biodefense field. The first is our HyperAcute immunotherapy technology, which has been licensed from us for the biodefense field. The second technology, based on a yellow fever virus, is in licensed from the University of California at San Francisco. The third technology is replication competent recombinant Vesicular Stomatitus Vaccine, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses.

BPS Grants and Contracts with the United Stated Government

On August 26, 2009, BPS received a grant from the NIH for the study of Rift Valley fever virus in the aggregate amount of $536,000, of which BPS has billed $534,000 through June 30, 2011 ($446,000 through

December 31, 2010). This grant provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The project period for this grant is from July 1, 2005 to June 30, 2011.

On April 6, 2010, BPS received a grant from the NIH for the study of yellow fever and arena viruses in the aggregate amount of $300,000, of which BPS has billed $300,000 through June 30, 2011 ($153,000 through December 31, 2010). On March 24, 2011, BPS received a second grant from the NIH to continue this study in the aggregate amount of $300,000, of which BPS has billed $42,000 through June 30, 2011. This grant provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. BPS retains the principal worldwide patent rights to any invention developed with support of the grant and the United States receives a royalty free license to use such inventions. The project period for this grant is from April 6, 2010 to March 31, 2012.

Contract between BPS and the DOD, dated July 31, 2009, as amended on April 21, 2010, for the study of Venezuelan equine encephalitis virus in the aggregate amount of $750,000, of which BPS has billed $665,000 through June 30, 2011 ($500,000 through December 31, 2010). This contract provides BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The period of performance for this contract is from July 31, 2009 through July 30, 2011.

Contract between BPS and the DOD, dated May 5, 2008, as amended February 12, 2009, for the study of adjuvant technology in the aggregate amount of $100,000, of which BPS has billed $100,000 through June 30, 2011 ($100,000 through December 31, 2010). This contract provided BPS with cost reimbursement for certain types of expenditures in return for research and development activities. The period of performance for this contract was from May 5, 2008 through May 1, 2009.

On September 25, 2009, BPS entered into a research and development contract with DOD for the study of a-Gal adjuvant technology for the biodefense field. The contract provides for reimbursements to BPS for certain research and development activities on a cost-plus-fixed-fee basis. The contract involves an initial two-year contract period during which BPS may receive reimbursements for aggregate amounts of up to approximately $3.7 million. Following the initial two-year period, DOD may exercise an option to extend the contract for an additional one-year period during which BPS may receive reimbursements for aggregate amounts of up to an additional approximately $3.5 million. As of June 30, 2011, BPS had submitted reimbursement requests for approximately $1.4 million for research and development performed under the contract during the initial contract period. BPS is permitted to retain ownership of inventions made by BPS under the contract subject to BPS's compliance with certain specified procedures.

Manufacturing

To date, we have manufactured our HyperAcute immunotherapies in our facilities in Ames, Iowa. We have transferred all of our manufacturing to a new facility also located in Ames. We believe this facility is adequate to supply all of the Phase 3 clinical trial drug requirements for at least the first two of our HyperAcute product candidates and initial commercial quantities of HyperAcute Pancreas in the United States. We are in the process of finalizing manufacturing process improvements that have the potential to significantly increase our production capacity.

We currently contract with Sigma-Aldrich Fine Chemicals, a division of Sigma-Aldrich Corporation, for the manufacture of our D-1MT product candidate. We believe that many suppliers would be available for the production of this product, if required. We currently have no plans to build our own manufacturing capacity to support this product.

Sales and Marketing

We currently own exclusive worldwide commercial rights to our HyperAcute and D-1MT immunotherapy product candidates. If we obtain approval for any of these product candidates, we intend to build a commercial infrastructure targeting oncologists and cancer centers in the United States. In addition, we may pursue partnerships or co-promotion arrangements with pharmaceutical and biotechnology companies to complement these efforts or for particular indications.

We expect that our commercial infrastructure would be comprised of a targeted specialty sales force led by several experienced sales management personnel, an internal marketing and medical affairs staff and a specialty distribution team. For our lead product candidate, HyperAcute Pancreas, we estimate that an initial sales force of approximately 50 to 100 representatives will be necessary to drive utilization at key institutions and cancer centers treating pancreatic cancer patients. Our sales infrastructure will also include managed markets personnel to establish and direct reimbursement activities with third-party payors, such as managed care organizations, group-purchasing organizations, oncology group networks and government accounts. We may need to hire personnel to fill some of these functions in advance of the approval of any of our product candidates. We currently have no sales and marketing or distribution capabilities or in-house personnel specializing in these functions.

Outside the United States, we may enter into out-licensing agreements with other pharmaceutical or biotechnology firms to develop and commercialize our product candidates in foreign markets.

Competition

The biopharmaceutical industry is highly competitive. Given the significant unmet patient need for new therapies, oncology is an area of focus for many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Immunotherapy Products for Cancer

The cancer immunotherapy landscape is broad but still in the early stages of development as a class of therapeutics with only one FDA-approved active cellular immunotherapy product, Dendreon Corporation's Provenge for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer. We estimate that there are over 100 cancer immunotherapy products in clinical development by approximately 70 public and private biotechnology and pharmaceutical companies. Altogether, trials of these product candidates target at least 23 different cancer types. Of this universe, several large public biopharmaceutical companies have approved or are developing cancer immunotherapy products, including Dendreon Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline plc, Merck & Co., Inc., Merck KGaA and Sanofi-Aventis. The cancer immunotherapy product landscape includes numerous immunotherapeutic approaches including but not limited to anti-idiotype, whole cell, DNA, peptide/antigen, viral, tumor lysate, shed antigens, and dendritic cell. To the extent applicable, cancer immunotherapies are also distinguished by whether or not they are derived from autologous or allogeneic sources. Different approaches to cancer immunotherapy design have the potential to confer corresponding advantages and disadvantages based on their respective immunostimulatory mechanisms, formulation characteristics, manufacturing requirements, and logistical demands.

HyperAcute Pancreas

There are several marketed products indicated for pancreatic cancer including Eli Lilly and Company's Gemzar, Astellas Pharma Inc.'s Tarceva, Teva Pharmaceutical Industries Limited's streptozocin, and fluorouracil, or 5-FU, and mitomycin which are marketed by several generic pharmaceutical firms. In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer including AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics Inc., Sanofi-Aventis, and Threshold Pharmaceuticals, Inc. among other companies.

HyperAcute Lung

There are numerous marketed therapeutics indicated for NSCLC including Roche Holding AG's Avastin, Eli Lilly's Alimta and Gemzar, Astellas Pharma's Tarceva, AstraZeneca PLC's Iressa, Sanofi-Aventis' Taxotere and Eloxatin, as well as generically available platinum-based chemotherapeutics (cisplatin and carboplatin) and mitotic inhibitors (paclitaxel and venorelbine) which are marketed by several generic pharmaceutical firms. In addition, there are a number of companies with active clinical trials ongoing in lung cancer including Abbott Laboratories, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim GmbH, BioNumerik Pharmaceuticals, Inc., Celgene, GlaxoSmithKline, NovaRx Corporation, Onyx Pharmaceuticals, Inc., Pfizer Inc., and Regeneron Pharmaceuticals, Inc. among other companies.

HyperAcute Melanoma

Excision is the preferred treatment for early stage, localized melanoma, and there are several marketed therapeutics indicated for advanced melanoma including Merck's Intron A, Novartis AG / Prometheus Laboratories Inc.'s Proleukin as well as cisplatin and dacarbazine, which are available through several generic pharmaceuticals firms. Bristol-Myers Squibb's immunotherapy ipilimumab was recently approved by the FDA as was Roche/Daiichi Sankyo's drug, vemurafenid. In addition, there are a number of companies with active clinical trials ongoing in advanced melanoma including Amgen, Astellas Pharma, Eli Lilly, Onyx, Roche, Synta Pharmaceuticals Corp., and Vical Inc., among other companies.

Intellectual Property

We believe that patent protection and trade secret protection are important to our business and that our future success will depend, in part, on our ability to maintain our technology licenses, maintain trade secret protection, obtain and maintain patents and operate without infringing the proprietary rights of others both in the United States and abroad. We believe that obtaining identical patents and protection periods for a given technology throughout all markets of the world will be difficult because of differences in patent laws. In addition, the protection provided by non-U.S. patents, if any, may be weaker than that provided by United States patents. We have established and continue to build proprietary positions for our HyperAcute Technology and our IDO pathway inhibitor technology in the United States and abroad. As of September 30, 2010, our patent portfolio included six patent families relating to our HyperAcute Technology and nineteen patent families relating to our IDO pathway inhibitor technology.

There are two principal families of patents and patent applications relating to our HyperAcute product candidates and HyperAcute Technology. The first patent family is exclusively licensed from Central Iowa Health System and includes five pending patent applications and 20 registered U.S. and foreign patents related to the HyperAcute Technology. This patent family is expected to provide basic composition of matter patent protection extending until 2023 and has already resulted in a granted patent in Europe (EP 1549353 B1), in Mexico (278681) and Canada (2501744), all covering pharmaceutical compositions for inhibiting pre-established tumor growth comprising attenuated allogeneic tumor cells modified with a-Gal. Similar composition claims as well as methods of use for treating pre-established tumors are currently being pursued in the U.S., China, Japan and Canada. One patent recently issued from

this family in the U.S. and contains claims to methods of making master cell banks of HyperAcute allogeneic cells (US 7,763,461).

The second principal family of patents is exclusively licensed from Drexel University and includes two U.S. patents (US 6,361,775 and US 5,879,675) relating to the use of a-Gal in viral and cancer vaccines. These patents expire in 2014 and 2016, respectively in the United States. Related patents in this family have also been granted in Canada and Europe and expire in 2015. We exclusively license from Central Iowa Health System or own several other patents relating to a-Gal technology, which we believe provide additional barriers to entry in the space occupied by our HyperAcute Technology. Additional coverage includes issued patents relating to gene therapy technology and the use of xenogeneic cells having a-Gal expiring in 2016; and an application issued in the United States (US Patent No. 7,998,486) and pending in Europe covering isolated tumor antigens comprising a-Gal residues and projected to expire in 2027.

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families exclusively licensed from the Medical College of Georgia. The first patent family contains three issued U.S. patents and two pending applications, all expiring in 2018. This family contains patents having claims to methods of increasing T cell activation (US 6,451,840) and methods of augmenting rejection of tumor cells (US 6,482,416) by administering an IDO inhibitor. The second patent family contains four pending applications and an issued U.S. patent (US 7,598,287) to methods of using D-1MT to treat cancer and provides exclusivity for this use until 2027. We are also actively pursuing pharmaceutical composition claims to D-1MT in the U.S. in a pending application from this family, and also claims to the use of D-1MT to activate T cells in Europe out of another Medical College of Georgia patent family that if granted, will provide exclusivity for this use in validated European countries until 2022. Related applications are allowed in Australia and are pending in Canada. We believe additional barriers to entry in the IDO space are provided through exclusive licenses with Lankenau Institute for Medical Research and various NewLink-owned inventions, in which we are pursuing patent protection for specific combination therapies targeting the IDO pathway, as well as protection for novel inhibitor compounds and potential second generation products.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the use or disclosure of confidential information. The agreements also oblige our employees, consultants, advisors and collaborators to assign or license to us ideas, developments, discoveries and inventions made by such persons in connection with their work with us. We cannot be sure that these agreements will maintain confidentiality, will prevent disclosure, or will protect our proprietary information or intellectual property, or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive and patents have been applied for by, and issued to, other parties relating to products or new technologies that may be competitive with those being developed by us. Therefore, our product candidates may give rise to claims that it infringes the patents or proprietary rights of other parties now or in the future. Furthermore, to the extent that we, our consultants, or manufacturing and research collaborators, use intellectual property owned by others in work performed for us, disputes may also arise as to the rights to such intellectual property or in related or resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that we are prevented from the development, manufacture or sale of products requiring such licenses. In addition, we could incur substantial costs in defending ourselves in legal proceedings instituted before patent and trademark offices in the United States, the European Union, or other ex-U.S. territories, or in a suit brought against us by a private party based on such patents or proprietary rights, or in a suit by us asserting our patent or proprietary rights against another party, even if the outcome is not adverse to us.

Licensing Agreements

Following are licensing agreements covering technologies and intellectual property rights useful to our HyperAcute product candidates and technologies:

Central Iowa Health System License Agreement

We are a party to a license agreement, or the CIHS Agreement, dated August 2, 2001 with the Central Iowa Health System, or CIHS. The CIHS Agreement grants to us an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to our HyperAcute immunotherapy technology. The license is subject to CIHS's retained right to use, and to permit other academic and research institutions to use, the CIHS patent rights and information for non-commercial bona fide research purposes. The license is also subject to certain rights of and obligations to the United States government under applicable law, to the extent that such intellectual property was created using funding provided by a United States federal agency. We may grant sublicenses under the license, so long as the sublicense is subordinate to, and complies with, the CIHS Agreement.

In partial consideration of the license under the CIHS Agreement, we entered into a stock purchase agreement with CIHS, under which we issued to CIHS shares of our common stock and granted CIHS certain rights related to ownership of such shares. In addition, we must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If we commercialize a licensed product, we also have the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments we must make to third parties. If we grant a sublicense under the licenses granted by CIHS, we must pay to CIHS a percentage of certain consideration paid by the sublicensee to us.

Under the CIHS Agreement, we must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets. As part of such efforts, we must deliver to CIHS certain information including an annual progress report detailing our progress towards commercial use of licensed products. At specific dates after the effective date we must satisfy certain obligations to conduct specified development on the licensed product, expend specified amounts on development of the licensed technology, or raise specific minimum amounts of equity capital. We are obligated to use commercially reasonable efforts to negotiate appropriate sponsored research programs with researchers at CIHS. If CIHS concludes that we have not met any of these obligations, and we fail to cure such failure, CIHS may either terminate the agreement or convert the license to a non-exclusive license. In addition, if CIHS determines that we have failed to use commercially reasonable efforts to, or to grant sublicenses to, develop or commercialize a licensed product in a particular field within the licensed field of use, CIHS may terminate, or convert the license to a non-exclusive license with respect to such particular field.

Unless terminated earlier, the CIHS Agreement shall remain in effect until the expiration of all of our royalty obligations under the agreement. Our royalty obligations expire on a country-by-country and a licensed product-by-licensed product basis upon the later of (i) the expiration of the last to expire valid claim within the licensed patents covering a licensed product in a country or (ii) 12 years following the first commercial sale of a licensed product in a country. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect that the last patent will expire under this agreement in 2023, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. We may terminate the agreement, or specific patents covered by the agreement, on written notice to CIHS or for CIHS' uncured material breach of the agreement. CIHS has the right to terminate for our uncured material breach of the agreement after written notice. Upon termination of the agreement we may sell our existing inventory of licensed products for a period of three months after such termination. We have the right to assign the CIHS Agreement to any affiliate or in connection with the transfer of all or substantially all of our assets

relating to the agreement, but any other assignment requires CIHS' written consent, which consent shall not be unreasonably withheld.

Drexel University License Agreement

We are party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants us, and our affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on a-Gal epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease. The license is subject to Drexel's retained right to use, and to permit other non-profit organizations to use, those patent rights and technical information for educational and non-commercial research purposes. The license is also subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that certain of such intellectual property were created using funding provided by a U.S. federal agency. We may grant sublicenses under the license, pursuant to a sublicense agreement in form acceptable to Drexel and subject to certain additional conditions and obligations.

In consideration of our license under the Drexel Agreement, we have paid and are obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately $1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if we grant a sublicense under the license granted by Drexel, we must pay Drexel a percentage of the consideration paid by the sublicensee to us.

In accordance with a development plan included in the Drexel Agreement, we are obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable. In addition, we must either market licensed products within five years of the date of the agreement, or demonstrate that we have made and continue to make bona fide, good faith, ongoing efforts to develop and market licensed products.

Unless terminated earlier, the Drexel Agreement shall remain in effect until the expiration or abandonment of all the licensed Drexel patents. Pending the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2015, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. We may terminate the Drexel Agreement on written notice to Drexel. Drexel has the right to terminate for the uncured breach of our obligations under the agreement or for certain other reasons. If the Drexel Agreement terminates we may, in certain circumstances, sell any remaining inventory of licensed products for a period of six months after termination. We may not assign the Drexel Agreement except with Drexel's written consent, not to be unreasonably withheld or delayed.

Following are licensing agreements covering technologies and intellectual property rights useful to our IDO pathway inhibitor technology and product candidate:

LIMR Exclusive License Agreement (IDO-1)

We are a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, and sell products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics. Such license is subject to LIMR's retained right to use such LIMR patent rights and technology for its non-commercial educational and research purposes. In addition, the license is

subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR Licenses, provided that each sublicense materially conforms to the IDO-1 Agreement and is expressly subject to its terms.

In consideration of such license grant, we are obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if we grant a sublicense under the IDO-1 Agreement, we must to pay to LIMR a percentage of the consideration received by us from the sublicensee.

Under the IDO-1 Agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If we breach our obligations and fail to cure such breach, LIMR may reduce our license to a non-exclusive license or revoke the license in its entirety.

Unless terminated earlier, the IDO-1 Agreement shall remain in effect until the expiration of the last licensed LIMR patents. Pending the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2024, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. LIMR may terminate the agreement for our failure to make payments due, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We have the right to assign the IDO-1 Agreement in connection with an acquisition, merger, consolidation, operation of law or the transfer of all or substantially all of our assets or equity relating to the agreement, but any other assignment requires the express prior written consent of LIMR, not to be unreasonably withheld.

Medical College of Georgia Research Institute License Agreement

We are a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

Such license is subject to MCGRI's retained right to use, and to permit its academic research collaborators to use, such MCGRI patent rights and technology for research and educational purposes. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under such license, subject to the prior approval of MCGRI, not to be unreasonably withheld or delayed.

In consideration of such license grant, we are obligated to pay to MCGRI specified license fees (including issuing shares of our common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if we grant a sublicense under the license granted by MCGRI, we must pay to MCGRI a percentage of the consideration we receive from the sublicensee.

Under the agreement, we are obligated to make certain investments toward the further development of licensed products within specified time periods. If we fail to make the required investment, MCGRI may convert our license in the oncology field to a non-exclusive license. In addition, if we fail to develop the licensed products in a non-cancer field, specifically infectious disease or diagnostics, MCGRI may convert our license in such field to a non-exclusive license.

Unless terminated earlier, the MCGRI Agreement will remain in effect until the expiration of the last licensed MCGRI patents. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2027, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. MCGRI may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. For a period of one year following the termination of the agreement, we may sell our licensed products that are fully manufactured and part of our normal inventory at the date of termination. We have the right to assign the MCGRI Agreement to our affiliates or in connection with the transfer of all or substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of MCGRI.

University of British Columbia License Agreement

We are a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants us an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants us an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.

Such license is subject to UBC's retained right to use such UBC patent rights and technology for research, scholarly publication, educational and non-commercial uses. We may grant sublicenses, other than naked cross-licenses, under the UBC license, provided that each sublicense is consistent with the terms and conditions of the UBC License and contains certain mandatory sublicensing provisions.

In consideration of such license grant, we must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.8 million per licensed product, and royalties in a range of less than 10% of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if we grant a sublicense under the licenses granted by UBC, we may be required to pay to UBC a percentage of certain consideration we receive from the sublicensee.

We are obligated to use our commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If we breach our obligations and fail to cure such breach, UBC may terminate this agreement. If we are diligently developing the licensed product in some therapeutic fields, but not in other therapeutic fields, UBC may require us to grant a sublicense in such other fields not being exploited by us to a third party that is able to develop the licensed product in such other fields.

Unless terminated earlier, the UBC License will remain in effect for 20 years or until the expiration of the last licensed UBC patents, whichever is later. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2027, excluding any patent term extensions or additional patents issued that are included under the license. UBC may terminate this agreement for our uncured material breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may not sell any inventory of the licensed product without the prior written consent of UBC. We have the right to assign the UBC Agreement to our affiliates or in connection with a merger, acquisition, or the transfer of all or

substantially all of our assets relating to the agreement, but any other assignment requires the prior written consent of UBC, not to be unreasonably withheld.

LIMR Exclusive License Agreement (IDO-2)

We are a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target Indoleamine 2,3 Dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR IDO-2 license, provided that each sublicense complies with the terms of the LIMR IDO-2 Agreement.

In consideration of such license grant, we have paid to LIMR an upfront license fee and annual license maintenance fees, and are obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately $1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us. The payment provisions of the LIMR IDO-2 Agreement provide that, in the event a product for which we have payment obligations under the LIMR IDO-2 Agreement is also covered by payment obligations under the LIMR IDO-1 Agreement, we will not be obligated to pay both such obligations but rather will pay to LIMR the higher of the amounts owed under the two agreements.

Under the LIMR IDO-2 Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the obligation, at our expense and in our reasonable discretion, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement. In addition, LIMR granted us the exclusive option to obtain exclusive, worldwide licenses on commercially reasonable terms to future inventions and discoveries of LIMR related to IDO-2 or inhibitors of IDO-2.

Concurrently with, and as an obligation under, the LIMR IDO-2 Agreement, we entered into a cooperative research and development agreement with LIMR, or the CRADA Agreement. Under the CRADA agreement, we agree to provide funding to LIMR in support of IDO research for one year and renewable at our option.

Unless terminated earlier, the LIMR IDO-2 Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2027, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

LIMR Exclusive License Agreement (IDO)

We are a party to a license agreement, or the LIMR IDO Agreement, dated April 23, 2009 with LIMR. The LIMR IDO Agreement grants us an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. Such license is subject to LIMR's retained non-exclusive right to use such LIMR patent rights and technical information for internal non-commercial, educational and research purposes only. In addition, the license is subject to certain rights of and obligations to the U.S. government under applicable law, to the extent that such intellectual property was created using funding provided by a U.S. federal agency. We may grant sublicenses under the LIMR IDO license, provided that each sublicense complies with the terms of the LIMR IDO Agreement.

In consideration of such license grant, we are obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately $610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for our royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if we grant a sublicense under the licenses granted by LIMR, we must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Under the LIMR IDO Agreement, we have agreed to use our commercially reasonable efforts to develop and exploit products covered by the license. We have the right and responsibility, at our expense and in our reasonable discretion, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement.

Unless terminated earlier, the LIMR IDO Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2029, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. We may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for our uncured breach, bankruptcy or similar proceedings. Upon termination of the agreement, we may sell our current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement. We may assign the LIMR IDO Agreement in connection with the transfer of all or substantially all of our assets or equity, or by reason of acquisition, merger, consolidation or operation of law, but any other assignment requires LIMR's written consent, which shall not be unreasonably withheld.

Bresagen Patent License Agreement

We are a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants us a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines in the U.S. In consideration of such license grant, we are obligated to pay Bresagen an up-front license fee and an annual license fee.

Unless terminated earlier, the Bresagen Agreement shall continue for an initial period of eight years, which may be extended an additional five years upon agreement of the parties. We may terminate the Agreement upon agreement in writing with Bresagen. Bresagen has the right to terminate for our uncured breach, insolvency, change of control without consent or similar proceedings. Upon termination of the agreement, all of our rights under the license are terminated. We may assign the Bresagen Agreement in connection with the transfer of all or substantially all of our assets by reason of acquisition, merger, purchase or otherwise with notice to Bresagen, but any other assignment requires Bresagen's written consent.

Following are licensing agreements to which BPS is a party covering technologies and intellectual property rights applicable to BPS's development of vaccines for the biodefense field:

Regents of the University of California License Agreement

BPS is a party to a license agreement dated July 29, 2008, or the California License, with the Regents of the University of California, or California. The California License grants BPS an exclusive, worldwide license, under specified California patent rights relating to technology based on yellow fever virus, to make, use, import, sell and offer for sale products that are covered by licensed patent rights in the field of human healthcare. The license is subject to California's retained right to use the California patent rights and technology for research purposes. The license is also subject to certain rights of and obligations to the United States government under applicable law. BPS may grant sublicenses under the California license, provided that each sublicense is consistent with the terms and conditions of the California License.

In consideration of the license grant, BPS must pay to California a specified license issue fee, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $285,000 per licensed product, and royalties as a low single-digit percentage of net sales of the licensed product, which royalty rate varies depending on the territory. In addition, if BPS grants a sublicense under the licenses granted by California, BPS may be required to pay to California a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines. If BPS breaches its obligations and fails to cure the breach, California may terminate the California License or reduce BPS's rights under the license.

Unless terminated earlier, the California License will remain in effect until the expiration or abandonment of the last of the California patent rights. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we expect the last patent will expire under this agreement in 2024, excluding any patent term extensions or additional patents issued that are included under the license. This agreement will terminate automatically upon the filing, by or against BPS, for relief under the United States Bankruptcy Code or upon the filing of a legal action, by or on behalf of BPS, claiming that any portion of the California License is invalid or unenforceable. California may terminate this agreement for BPS's uncured material breach. BPS may terminate this agreement upon written notice to California. Upon termination of the agreement, BPS may sell any previously made licensed product for a period of 120 days after termination. BPS has the right to assign the California License to its affiliates or in connection with a merger, acquisition, or the transfer of all or substantially all of its assets relating to the agreement, but any other assignment requires the prior written consent of California.

Her Majesty the Queen in Right of Canada License Agreement

BPS is a party to a license agreement dated May 4, 2010, or the Canada License, with the Her Majesty the Queen in Right of Canada, or Canada. The Canada License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified Canada patent rights relating to technology based on rVSV. The license is subject to Canada's retained right to use the Canada patent rights and technology to improve the patent rights, carryout educational purposes, and development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may grant sublicenses under the Canada license, provided that each sublicense is consistent with the terms and conditions of the Canada License and contain certain mandatory sublicensing provisions.

In consideration of the license grant, BPS must pay to Canada a specified patent and signing fees, annual license maintenance fees, patent prosecution costs, potential milestone payments in an aggregate amount up to approximately C$205,000 per licensed product, and royalties as a low single-digit percentage of the sales price of the licensed products sold by BPS, which royalty rate varies depending on the type of licensed product. In addition, if BPS grants a sublicense under the licenses granted by Canada, BPS is

required to pay to Canada a percentage of certain consideration BPS receives from the sublicensee. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products. If BPS breaches its obligations and fails to cure the breach, Canada may terminate the Canada License.

Unless terminated earlier, the Canada License will remain in effect until the expiration of the last of the Canada patent rights. Pending the status of certain patent applications and the payment of appropriate maintenance, renewal, annuity or other governmental fees, we currently expect the last patent will expire under this agreement in 2023, excluding any patent term adjustments or patent term extensions or additional patents issued that are included under the license. Canada may terminate this agreement for BPS's failure to use commercially reasonable efforts to commercialize, failure to pay, breach of confidentiality, cessation of business, criminal conviction or other breach of its obligations under the agreement. BPS may not assign the Canada License to a third party without the prior written consent of Canada, not to be unreasonably withheld. This agreement will terminate automatically if BPS assigns the Canada License without prior written consent or if BPS files for bankruptcy or similar proceedings.

Government Regulation

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act, or FDC Act, and the Public Health Service Act, among others.

The FDC Act and other federal and state statutes and regulations govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time consuming.

FDA Approval Process

In the United States, pharmaceutical products, including biologics, are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, or biologic license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices, or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs, which are applications for marketing approval, are typically conducted in three sequential Phases, but the Phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. Before proceeding with a Phase 3 clinical trial, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as a Special Protocol Assessment, or SPA. SPAs help establish up front agreement with the FDA about the adequacy of the design of a clinical trial to support a regulatory approval, but the agreement is not binding if new circumstances arise. In addition, even if an SPA remains in place and the trial meets its endpoints with statistical significance, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other burdensome post-approval requirements or limitations.

In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers. Since these patients already have the target disease, these studies may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these trials are frequently referred to as Phase 1B clinical trials. Additionally, when product candidates can do damage to normal cells, it is not ethical to administer such drugs to healthy patients in a Phase 1 clinical trial. After completion of the required clinical testing, an NDA or, in the case of a biologic, a BLA, is prepared and submitted to the FDA. FDA approval of the marketing application is required before marketing of the product may begin in the U.S. The marketing application must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The

FDA has agreed to certain performance goals in the review of marketing applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a marketing application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices, or cGMPs, is satisfactory and the marketing application (the NDA or, in the case of biologics, the BLA) contains data that provide substantial evidence that the drug is safe and effective in the indication studied. Manufacturers of biologics also must comply with FDA's general biological product standards.

After the FDA evaluates the marketing application and the manufacturing facilities, it issues an approval letter, or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the marketing application, FDA will re-initiate review. If it is satisfied that the deficiencies have been addressed, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual for the FDA to issue a complete response letter because it believes that the drug is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of approval of the marketing application, the FDA may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Fast Track Designation

Congress enacted the Food and Drug Administration Modernization Act of 1997, or the Modernization Act, in part to ensure the availability of safe and effective drugs, biologics and medical devices by expediting the development and review for certain new products. The Modernization Act establishes a statutory program for the review of Fast Track products, including biologics. A Fast Track product is defined as a new drug or biologic intended for the treatment of a serious or life-threatening condition that demonstrates the potential to address unmet medical needs for this condition. Under the Fast Track program, the sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a Fast Track product at any time during the development of the product, prior to a new drug application submission. Fast Track designation enables a company to file their application for approval on a rolling basis and potentially qualify for priority review.

The FDA may condition approval of an application for a Fast Track product on a commitment to do post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint and require prior review of all promotional materials. In addition, the FDA may withdraw approval of a Fast Track product in an expedited manner on a number of grounds, including the sponsor's failure to conduct any required post-approval study in a timely manner. On October 1, 2010 the FDA approved our application for Fast Track product designation for HyperAcute Pancreas.

Orphan Drug Designation

The Company was granted Orphan Drug designation for HyperAcute Pancreas on October 21, 2010 by the FDA. The FDA grants Orphan Drug designation to drugs intended to treat a rare disease or condition, which for this program is defined as having a prevalence of less than 200,000 individuals in the United States. Now that the FDA has granted us Orphan Drug designation, the generic identity of our therapeutic agent and its potential orphan use will be disclosed publicly by the FDA. Orphan drug exclusive marketing rights may be lost if the FDA determines that our request for designation was materially defective or if we are unable to assure sufficient quantity of our drug.

Orphan drug designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives the first approval for the indication for which it has designation, the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years in the United States. Additional benefits of Orphan Drug designation include clinical tax research incentives and exemption from application filing fees. Although obtaining approval to market a product with orphan drug exclusivity may be advantageous, we cannot be certain:

- that we will be the first to obtain approval for any other drugs or indications for which we obtain Orphan Drug designation;
- that Orphan Drug designation will result in any commercial advantage or reduce competition; or
- that the limited exceptions to this exclusivity will not be invoked by the FDA.

Accelerated Approval Based on Surrogate Endpoint

The Modernization Act provides that the FDA can base approval of a marketing application for a Fast Track product on an effect on a surrogate endpoint, or on another endpoint that is reasonably likely to predict clinical benefit. Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. We do not intend to seek approval for HyperAcute Pancreas based on a surrogate endpoint, but may seek approval based on surrogate endpoints for other indications in the future.

The Hatch-Waxman Act

In seeking approval for marketing of a drug or biologic through an NDA or BLA, respectively, applicants are required to list with the FDA each patent with claims that cover the applicant's product or FDA approved method of using this product. Upon approval of a product, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than

the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification notification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

Other Regulatory Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement, or in the case of biologics, a new BLA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs. We cannot be certain that the FDA or any other regulatory agency will grant approval for our product candidates for any other indications or any other product candidate for any indication on a timely basis, if at all.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their

subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to access compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Priority Review

Under the FDA policies, a drug or biologic candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA or BLA is submitted, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A Fast Track designated drug or biologic candidate would ordinarily meet the FDA's criteria for priority review.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Federal and State Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the marketplace.

Regulation in the European Union

Drugs are also subject to extensive regulation outside of the United States. In the E.U., for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the E.U. (which includes most major countries in Europe). If this procedure is not used, approval in one country of the E.U. can be used to obtain approval in another country of the E.U. under two simplified application processes, the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

Similar to the United States, a system for Orphan Drug designation exists in the E.U. Orphan designation does not shorten the regulatory review and approval process for an orphan drug, nor does it give that drug any advantage in the regulatory review and approval process. However, if an orphan drug later receives approval for the indication for which it has designation, the relevant regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for ten years in the E.U.

Price Controls

In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, the Medicare program is administered by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. Coverage and reimbursement for products and services under Medicare are determined pursuant to regulations promulgated by CMS and pursuant to CMS's subregulatory coverage and reimbursement determinations. It is difficult to predict how CMS may apply those regulations and subregulatory determinations to newly approved products, especially novel products, and those regulations and interpretive determinations are subject to change. Moreover, the methodology under which CMS makes coverage and reimbursement determinations is subject to change, particularly because of budgetary pressures facing the Medicare program. For example, the Modernization Act provides for a change in reimbursement methodology that reduces the Medicare reimbursement rates for many drugs, including oncology therapeutics. Medicare regulations and interpretive determinations also may determine who may be reimbursed for certain services.

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and

passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and regulations now or in the future.

Legal Proceedings

We are not currently a party to any legal proceedings.

Employees

As of June 30, 2011, we had 78 employees. None of our employees are subject to a collective bargaining agreement or represented by a labor or trade union, and we believe that our relations with our employees are good.

Facilities

Our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. In June 2010, we completed the expansion of a 22,500 square foot facility, which includes executive offices as well as approximately 14,000 feet dedicated to manufacturing, testing and product storage. The manufacturing portion of the facility became operational on October 17, 2010. The lease expires January 31, 2015, and we have the option to extend the lease for three additional five-year periods upon the same terms as the base lease. In addition, we continue to occupy a small pilot manufacturing and office facility in the same research park, which we lease on a month-to-month basis.

MANAGEMENT

The following table sets forth the name, age and position of each of our executive officers and directors as of December 31, 2010.

Name	Age	Position
Executive Officers		
Charles J. Link, Jr., M.D.	52	Chief Executive Officer, Chief Scientific Officer, Chairman of the Board
Nicholas N. Vahanian, M.D.	44	President, Chief Medical Officer
Gordon H. Link, Jr.	57	Chief Financial Officer
Kenneth Lynn	58	Executive Vice President of Business Development
Significant Employees		
Mario Mautino, Ph.D.	45	Vice President—Drug Discovery Module, Intellectual Property Officer
W. Jay Ramsey, M.D., Ph.D.	54	Quality Assurance Officer
Non-Employee Directors		
Thomas A. Raffin, M.D.	64	Director, (1), (2) and (4)
Sarah Alexander, M.D., F.A.C.P.	67	Director, (2)
David J. Lundquist	69	Director, (3)
Joseph Saluri	44	Director, (1) and (2)
Ernest J. Talarico, III	40	Director, (1) and (3)
Paul R. Edick	55	Director, (3)

(1) Member of the Compensation Committee.

(2) Member of the Nominating and Governance Committee.

(3) Member of the Audit Committee.

(4) Lead Independent Director.

Executive Officers

Charles J. Link, Jr., M.D. founded the Company in 1999 and has served as Chairman of the Board and Chief Scientific Officer since inception in 1999. He served as President from 2001 to 2009 and has served as Chief Executive Officer since 2003. Dr. Link has also served as Chairman and Chief Executive Officer of BioProtection Systems Corporation from 2005 and was its Chief Scientific Officer from 2005 to 2009. Dr. Link has been a practicing oncologist at the Medical Oncology and Hematology Associates of Iowa since 1995. From 1995 to 2003, Dr. Link served as the Director of the John Stoddard Cancer Research Institute, which he co-founded. Dr. Link served as a Medical Oncology Clinical Fellow at the NCI, National Institutes of Health, or NIH, from 1988 to 1991. Dr. Link attended the U.S. Air Force Academy from 1977 to 1980. Dr. Link holds a B.A. from Stanford University, an M.D. from Stanford University School of Medicine and is certified in Internal Medicine by the American Board of Internal Medicine and has previously been certified in Medical Oncology.

The Nominating and Corporate Governance Committee believes that Dr. Link's extensive experience with the Company, as founder and as Chief Scientific Officer and Chairman of the Board since inception, brings both strategic vision and continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Dr. Link's prior experience as a NCI trained oncologist and Director of the Stoddard Cancer Research Institute provides him with substantial expertise in drug discovery and development, which are important to the Board.

Nicholas N. Vahanian, M.D. has served as our Chief Medical Officer since 2001, Chief Operations Officer since 2003 and President since 2009. Dr. Vahanian served as a research scientist at the NCI from 1992 to 1994 and at the National Center for Human Genome Research, NIH from 1994 to 1995. He completed his Molecular Oncology Fellowship at the John Stoddard Cancer Research Institute from 1999 to 2000. Dr. Vahanian holds a B.S. in Biology from Virginia Commonwealth University. Dr. Vahanian attended St. Barthalomew's and Royal London Hospital Medical College. He also holds an M.B.A. from the University of Notre Dame.

Gordon H. Link, Jr. has served as our Chief Financial Officer since 2008. Previously, Mr. Link worked for Tapestry Pharmaceuticals, Inc., or Tapestry, as Chief Executive Officer from April to July 2008, Senior Vice President and Chief Financial Officer from 2002 through 2008, President of the Genomics Division from 2000 to 2002 and Vice President and Chief Financial Officer from 1993 to 2002. At Tapestry, Mr. Link directed a staff of five to ten individuals in areas of accounting, cash management, financial planning and analysis, risk management, financial reporting and investor relations. Mr. Link also worked with Tapestry's Board of Directors on financial, business and corporate development matters and coordinated Tapestry's initial public offering and subsequent follow-on public offerings of common stock. On April 4, 2008, the Tapestry Board of Directors appointed Mr. Link as Chief Executive Officer to manage the winding up of Tapestry in bankruptcy. Tapestry filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code on March 19, 2009. Prior to joining Tapestry, Mr. Link served as Corporate Controller of Synergen, Inc., Treasurer of the Syntex-Synergen Neuroscience Joint Venture, Treasurer of Synergen Development Corporation and Audit Manager with Deloitte & Touche USA LLP. Mr. Link received a B.S. from Rensselaer Polytechnic Institute and a B.A. in accounting from Metropolitan State College. Mr. Link is not related to our Chief Executive Officer, Dr. Charles Link.

Kenneth Lynn joined the Company as Senior Vice President of Business Development in February 2008 and has served as Executive Vice President of Business Development since February 2009. From 2006 to 2008, Mr. Lynn was employed as Executive Vice President, Strategy and Policy, of Kansas Technology Enterprise Corporation. From 2004 to 2006, Mr. Lynn worked for the Kauffman Foundation, where he served as President of the Kauffman Innovation Network, a nonprofit corporation established and supported by the Kauffman Foundation to promote the advancement of science and technology-based innovation generated by university researchers. Mr. Lynn was Senior Vice President of Corporate Development and Legal Affairs with RxKinetix, Inc. from 2000 to 2002, where he led the opportunities assessment and strategic planning process, coordinated development of the business plan, and evaluated and negotiated partnership and licensing agreements. He was Senior Vice President, Corporate Development and Legal Affairs with Valentis, Inc. from 1999 to 2000, where he supervised the business development and legal staff, evaluated and negotiated corporate transactions and partnering opportunities, and managed existing strategic alliances. From 1993 to 1998, Mr. Lynn worked for Cortech, Inc., a publicly traded company, where he progressed from Vice President of Business Development and General Counsel to Chairman and Chief Executive Officer. From 1991 to 1993, Mr. Lynn was Vice President and General Counsel of U.S. Bioscience, Inc. From 1984 to 1991, he served as Corporate Counsel with Marion Laboratories (now Sanofi-Aventis). Mr. Lynn holds a B.A. degree in history from Washburn University, a J.D. from the University of Kansas, and an M.B.A. from Rockhurst University.

Significant Employees

Mario Mautino, Ph.D. has served as our Vice President for the Drug Discovery Module since 2007 and as our Intellectual Property Officer since 2002, and served as a Senior Scientist at NewLink Genetics from 2001 to 2007. He received his Licenciate in Biological Chemistry in 1990 and his Ph.D. in Molecular Genetics at the University of Cordoba, Argentina in 1995. He performed one year of post-doctoral training at the National University of Cordoba and five years of post-doctoral work in human gene therapy at the Clinical Gene Therapy Branch, NIH.

W. Jay Ramsey, M.D., Ph.D. has served as our Clinical and Regulatory Compliance Officer since 2006 and served as our Senior Medical Scientist from 2000 to 2006. Prior to joining the Company, Dr. Ramsey served as Clinical Fellow of the Clinical Gene Therapy Branch, National Human Genome Research Institute, NIH from 1995 to 2000, and Clinical Fellow of the Metabolism Branch of the NCI from 1992 to 1995. Dr. Ramsey received his Ph.D. in Cell Biology from the Baylor College of Medicine in Houston, TX and his M.D. from University of Texas Medical Branch at Galveston.

Non-Employee Directors

Thomas A. Raffin, M.D. has served as a member of the Board of Directors since 1999. Dr. Raffin has spent 30 years on the faculty at Stanford University School of Medicine, where he is the Colleen and Robert Haas Professor Emeritus of Medicine and Biomedical Ethics. Over the past two decades, Dr. Raffin has worked extensively in the healthcare and medical device business sectors and was an advisor to Cell Therapeutics Inc. (1993-1997), Broncus Technologies (1997-2004), Medica (1998-2002), and Inhale Technologies (1998-2001). He co-founded Rigel Pharmaceuticals, a publicly traded company, in 1996. In 2001, he co-founded Telegraph Hill Partners, a San Francisco life sciences private equity firm as a General Partner. Dr. Raffin has been a director of the following Telegraph Hill Partners private portfolio companies: AngioScore, Confirma, Freedom Innovations, LDR, and PneumRK. Dr. Raffin received a B.A. from Stanford University and an M.D. from Stanford University School of Medicine and did his medical residency at the Peter Bent Brigham Hospital (now Brigham and Women's Hospital) in Boston.

The Nominating and Corporate Governance Committee believes that Dr. Raffin's experience with the Company, as a director since inception, brings continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Dr. Raffin's prior experience as a founder of Rigel Pharmaceuticals and as a venture capitalist and board member of development stage biotechnology companies provides important background to the Board in drug development, finance, corporate development, and overall strategy.

Sarah Alexander, M.D., F.A.C.P. has served as a director since 2006. Dr. Alexander is certified by the American Board of Internal Medicine in Internal Medicine, Hematology and Medical Oncology. She has been a practicing hematologist and oncologist since 1975 and worked with the Medical Oncology and Hematology Associates in Des Moines since 1989. At present, she is a Medical Oncologist and Hematologist at the Des Moines Veterans Administration Hospital. Dr. Alexander's undergraduate work was completed at Christian Medical College, Vellore, Madras, India, her residency in Internal Medicine was completed at the V. A. Hospital in New Orleans, Louisiana, and her fellowship in Medical Oncology and Hematology was completed in at Emory University School of Medicine.

The Nominating and Corporate Governance Committee believes that Dr. Alexander's experience as a practicing medical oncologist and as an investigator in clinical trials brings an important perspective to the Board, as most of our product candidates under development are targeted at cancer.

David J. Lundquist has served as a director since 2005. Since 1996, Mr. Lundquist has served as a Partner of Lundquist, Schiltz & Associates, a firm in the fee-only investment advisory business. From 1991 to 1996, Mr. Lundquist was Vice Chairman of New Heritage Associates, a company engaged in the acquisition and operation of cable television systems. From 1980 to 1990, Mr. Lundquist was Executive Vice President—Finance of Heritage Communications, Inc. Mr. Lundquist is currently a director of Da-Lite Screen Company, Genesis Systems Group, Marketlink and G-Sky. Mr. Lundquist holds a B.A. from the University of Minnesota and an M.B.A. from Stanford University Graduate School of Business.

The Nominating and Corporate Governance Committee believes that Mr. Lundquist's ten years of experience as a Executive Vice President—Finance of a public company provides important experience in corporate finance and provides the background necessary for Mr. Lundquist to chair our Audit Committee and to serve as an "audit committee financial expert." In addition, Mr. Lundquist's operational experience

in rapidly growing companies and transactional experience in both financing and strategic transactions may be helpful to the Company in the future.

Joseph Saluri has served as a director since May 2010. Mr. Saluri has served as Vice President and General Counsel for Stine Seed Company and its affiliates since July 1999. As part of his duties for Stine, he works to establish collaborative licensing, research and marketing alliances with international biotechnology and agribusiness companies, in addition to managing the legal and intellectual property affairs for the Stine Companies. Previous to his employment with Stine, Mr. Saluri was an attorney and solicitor at law with Nicholas Critelli Associates, PC, in Des Moines and London. Mr. Saluri received a B.S./B.A. from Drake University and a J.D. from Drake University Law School.

The Nominating and Corporate Governance Committee believes that Mr. Saluri's extensive experience as legal counsel to a large private company provides important experience in corporate finance and provides the background necessary for Mr. Saluri to serve as a member of our Audit Committee and our Nominating and Corporate Governance Committee. In addition, Mr. Saluri's operational experience in rapidly growing companies and transactional experience in both financing and strategic transactions may be helpful to the Company in the future.

Ernest J. Talarico, III has served as a director since 1999. Mr. Talarico has worked for Mesirow Financial Holdings, Inc., a diversified financial services firm headquartered in Chicago, Illinois since 1998, where he has been a Managing Director since June 2008. Prior to becoming Managing Director, Mr. Talarico served as Senior Vice President from 2005 to 2008, Vice President from 2003 to 2005 and Investment Executive from 1998 to 2003. Mr. Talarico specializes in financial planning and asset allocation, as well as other wealth accumulation and preservation strategies for individuals and businesses. Mr. Talarico sits on several boards and committees, including the Mutual Fund Committee at Mesirow Financial and the Select Advisory Board and Committee at Mesirow Financial. Mr. Talarico has also been the Chairman for the local chapter of the Cystic Fibrosis Foundation and the Founder and Chairman of the Talarico Ataxia Foundation. Mr. Talarico holds a bachelor's degree from the University of Iowa as well as licenses in equities, options and managed futures.

The Nominating and Corporate Governance Committee believes that Mr. Talarico's experience with the Company, as a director since inception, brings continuity to the Board. In addition, the Nominating and Corporate Governance Committee believes that Mr. Talarico's extensive experience in the investment management business provides important experience in corporate finance and investor relations and provides the background necessary for him to serve as a member of our Audit Committee.

Paul R. Edick was appointed to the Board of Directors on July 29, 2011. Since July 2010, Mr. Edick has been the Chief Executive Officer of Durata Therapeutics, a start-up biopharmaceutical company. From 2008 to 2010, Mr. Edick was Chief Executive Officer of Ganic Pharmaceuticals, a specialty pharmaceutical company. From 2006 to 2008, Mr. Edick was Chief Executive Officer of MedPointe Healthcare Inc., a specialty pharmaceutical company until its acquisition. From 2002 to 2006, Mr. Edick was President of MedPointe Healthcare Inc. From 1994 to 2002, Mr. Edick worked in a series of positions at G. D. Searle and its acquirer, Pharmacia Corporation, where he led G. D. Searle's U.S. managed care organization from 1994 to 1995, its U.S. marketing organization from 1995 to 1996 and its Global Pain & Inflammation Business from 1996 to 1997. In 1998, Mr. Edick was named G. D. Searle's VP-Canada & Latin America. In 1999, Mr. Edick became President of Asia Pacific, Canada & Latin America. In 2000, upon Pharmacia's acquisition of G. D. Searle, Mr. Edick was named Group Vice President and President, Asia Pacific/Latin America at Pharmacia. From 2008 to 2011, Mr. Edick was a director and Chairman of the Board of Directors of Life Cycle Pharma, a public technology based biotech located in Copenhagen, Denmark. In addition, Mr. Edick has been a director of Amerita, Inc. since 2000 and was a director of Informed Medical Communications from 2006 to 2011. Mr. Edick holds a B.A. in Psychology from Hamilton College, Clinton.

The Nominating and Corporate Governance Committee believes that Mr. Edick's extensive pharmaceutical industry experience, including leading the growth of the commercial business and development of a clinical stage portfolio at MedPointe Healthcare Inc., negotiating the sale of MedPointe Healthcare Inc. to Meda AB, Sweden and developing G. D. Searle's commercialization and launch plan for Celebrex®, give him the qualifications and skills to serve as a director, and are particularly important as the Company focuses on development and commercialization of its product candidates.

Scientific Advisors

We have established a scientific advisory board comprised of leading experts in their fields. We regularly seek advice and input from these experienced scientific leaders on matters related to our research and development programs. The members of our scientific advisory board consist of experts across a range of key disciplines relevant to our programs and science. We intend to continue to leverage the broad expertise of our advisors by seeking their counsel on important topics relating to our drug discovery and development programs. Some members of our scientific advisory board enter into consulting agreements with us covering their respective financial arrangements and confidentiality, non-disclosure and proprietary rights matters and own or have owned shares of our common stock or options to purchase shares of our common stock.

All of the scientific advisors are employed by or have consulting arrangements with other entities and devote only a small portion of their time to us. Our current advisors are:

Name	Professional Affiliation
Robert B. Belshe, M.D.	Director of the Division of Infectious Diseases and Immunology at Saint Louis University.
Michael Blaese, M.D.	Research Director of the Fund for Inherited Disease Research, Founder and President of PreGentis, Medical Director of the Immune Deficiency Foundation and Administrator of the U.S. Immunodeficiency Network Research Consortium.
Richard Burt, M.D.	Director of Allogeneic Bone Marrow Transplantation for Northwestern Medical Center in Chicago, Illinois and Assistant Professor at Northwestern University School of Medicine.
Richard C. Larock, Ph.D.	Distinguished Professor of Organic Chemistry at Iowa State University.
Kevin Legge, Ph.D.	Assistant Professor of Pathology at the University of Iowa Carver College of Medicine.
Andrew Mellor, Ph.D.	Professor of Medicine and Georgia Research Alliance Eminent Scholar in Immunogenetics at the Medical College of Georgia.
David Munn, M.D.	Professor of Pediatric Hematology-Oncology at the Medical College of Georgia. Head of the Cancer Immunotherapy program in the Cancer Research Center at MCG.
Nicola Pohl, Ph.D.	Associate Professor and Caldwell Chair of Chemistry at Iowa State University.
George Prendergast, Ph.D.	Professor and President/CEO of the Lankenau Institute for Medical Research.

Board Composition and Election of Directors

Our Board of Directors currently consists of five non-employee members and our Chief Executive Officer, Dr. Charles Link. Our Board of Directors has determined that all of our directors, other than Dr. Link, are independent within the meaning of applicable NASDAQ listing standards.

We have initiated the process of recruiting an additional director. Among other qualifications, we are seeking a director who could serve as a member of our Audit Committee.

Effective upon the completion of this offering, we will divide our Board of Directors into three classes, as follows:

- Class I, which will consist of Dr. Alexander and Mr. Talarico, and whose terms will expire at our first annual meeting of stockholders to be held after the completion of this offering;
- Class II, which will consist of Mr. Lundquist, Mr. Edick and Mr. Saluri, and whose terms will expire at our second annual meeting of stockholders to be held after the completion of this offering; and
- Class III, which will consist of Dr. Charles Link and Dr. Raffin, and whose terms will expire at our third annual meeting of stockholders to be held after the completion of this offering.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the Board of Directors may have the effect of delaying or preventing changes in our control or management. Under our certificate of incorporation to be in effect upon the closing of this offering, our directors may be removed only for cause, which may be effected by the affirmative vote of the holders of $66^{2}/_{3}$% of our voting stock.

Board Committees

Upon the completion of this offering, our Board of Directors will have an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. At that time, each of these committees will have adopted a written charter that will be available on our corporate website. The composition and primary responsibilities of each committee are described below.

Audit Committee

Upon the completion of this offering, the members of our Audit Committee will be Mr. Lundquist, Mr. Edick and Mr. Talarico. Mr. Lundquist will serve as chairman of the Audit Committee. Our Board of Directors has determined that each member of the Audit Committee meets the independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, or the Exchange Act, and NASDAQ listing standards, except for Mr. Talarico. Our Board of Directors has also determined that Mr. Lundquist qualifies as an audit committee financial expert within the meaning of Securities and Exchange Commission, or SEC, regulations.

The primary purpose of the Audit Committee is to discharge the responsibilities of our Board of Directors with respect to our accounting, financial and other reporting and internal control practices and to oversee our independent registered public accounting firm. Specific responsibilities of our Audit Committee include:

- evaluating the performance of our independent registered public accounting firm and determining whether to retain or terminate their services;

- determining and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services, other than immaterial aggregate amounts of non-audit services as excepted under applicable laws and rules;
- reviewing and discussing with management and our independent registered public accounting firm the results of the annual audit and the independent registered public accounting firm's review of our annual and quarterly financial statements and reports;
- reviewing with management and our independent registered public accounting firm significant issues that arise regarding accounting principles and financial statement presentation;
- conferring with management and our independent registered public accounting firm regarding the scope, adequacy and effectiveness of our internal control over financial reporting; and
- establishing procedures for the receipt, retention and treatment of any complaints we receive regarding accounting, internal control or auditing matters.

Compensation Committee

Upon the completion of this offering, the members of our Compensation Committee will be Dr. Raffin, Mr. Saluri and Mr. Talarico. Dr. Raffin will serve as chairman of the Compensation Committee. Our Board has determined that each member of the Compensation Committee is independent within the meaning of applicable NASDAQ listing standards, is a non-employee director as defined in Rule 16b-3 under the Exchange Act and is an outside director as that term is defined in Section 162(m) of the Internal Revenue Code of 1986. The purpose of our Compensation Committee is to discharge the responsibilities of our Board of Directors to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers and other senior management. Specific responsibilities of our Compensation Committee include:

- determining the compensation and other terms of employment of our executive officers and reviewing and approving corporate performance goals and objectives relevant to such compensation;
- evaluating and recommending to our Board of Directors the compensation plans and programs advisable for us, and evaluating and recommending the modification or termination of existing plans and programs; and
- reviewing and approving the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangements for our executive officers.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Dr. Alexander, Dr. Raffin and Mr. Saluri. Dr. Raffin serves as chairman of the Nominating and Corporate Governance Committee. Each member of the Nominating and Corporate Governance Committee is independent within the meaning of applicable NASDAQ listing standards. The specific responsibilities of our Nominating and Corporate Governance Committee include:

- identifying, reviewing, evaluating and recommending for selection candidates for membership to our Board of Directors;
- reviewing, evaluating and considering the recommendation for nomination of incumbent members of our Board of Directors for reelection to our Board of Directors and monitoring the size of our Board of Directors;
- evaluating nominations by stockholders of candidates for election to our Board of Directors;
- reviewing, discussing and reporting to our Board of Directors an assessment of our board's performance; and
- determining adherence to our corporate governance documents.

Lead Independent Director

Dr. Raffin has been appointed as our lead independent director. As lead independent director, Dr. Raffin will work with our Chief Executive Officer to develop the agenda for meetings of the Board of Directors and with committee chairs to develop the agendas for meetings of committees. He will also chair the executive session of Board meetings at which officers are not present and will oversee the Board's annual evaluation of our Chief Executive Officer's performance.

Compensation Committee Interlocks and Insider Participation

For the fiscal year ended December 31, 2009, members of the Board's Compensation Committee consisted of Dr. Raffin and Mr. Talarico and for the fiscal year ended December 31, 2010, members of the Board's Compensation Committee consisted of Dr. Raffin, Mr. Talarico, and Mr. Saluri. None of the members of the Compensation Committee is currently, or has ever been at any time since the Company's formation, one of the Company's officers or employees. None of our officers currently serve, nor have they served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more officers serving as a member of our Board of Directors or Compensation Committee.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions. Following this offering, a current copy of the code will be posted on the Corporate Governance section of our website, *www.linkp.com*.

EXECUTIVE AND DIRECTOR COMPENSATION

The following discussion and analysis of compensation arrangements of our named executive officers for our fiscal years ended December 31, 2009 and 2010 and the six-month period ending June 30, 2011 should be read together with the compensation tables and related disclosures set forth below. This discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion.

Compensation Discussion and Analysis

Our executive compensation program is designed to help us attract talented individuals to manage and operate our business, to reward those individuals fairly over time and to retain those individuals who continue to meet our high expectations. The goals of our executive compensation program are to align our executive officers' compensation with our business objectives and the interests of our stockholders, to incentivize and reward our executive officers for our success and to reflect the teamwork philosophy of our executive management team. To achieve these goals, we have established executive compensation and benefit packages that are based on a mix of base salary, cash incentive payments and equity-based awards and severance and change in control benefits. Our executive compensation program is also intended to make us competitive in the biopharmaceutical industry, where there is significant competition for talented employees, and to be fair relative to other professionals within our organization.

Compensation Objectives

Our compensation program is designed to enable us to attract and retain executives with the skills and experience necessary to execute our business plan, to provide short-term incentives to accomplish specific annual goals defined by the Board of Directors, and to provide long-term incentives to build shareholder value.

Role of Our President and Chief Executive Officer in Setting Executive Compensation

We initially establish executive officers' compensation arrangements when negotiating the terms of employment when they join the Company. We generally include these initial compensation terms in an offer letter with the executive. Each year we review executive compensation and the mix of elements used to compensate our executive officers. In connection with each annual review cycle, Dr. Charles Link, our Chief Executive Officer, meets with those officers who report directly to him to discuss the Company's accomplishments during the year and the individual's performance and contributions over the prior year. Based on these discussions, our Chief Executive Officer then develops a set of compensation recommendations for submission to our Compensation Committee. The Compensation Committee uses these recommendations, its own judgment and experience, and the resources and tools described below to determine the appropriate mix of compensation for each of our executive officers. Our Chief Executive Officer does not participate in the determination of his own compensation.

Role of Our Board and Compensation Committee in Setting Executive Compensation

Our Board of Directors has established a Compensation Committee for the purpose of making recommendations to the full Board of Directors regarding compensation decisions for our executive officers. The Compensation Committee currently consists of Dr. Raffin, Mr. Saluri and Mr. Talarico. In carrying out its responsibilities, our Compensation Committee receives and evaluates the compensation recommendations made by our Chief Executive Officer. None of our executive officers participates in the discussions regarding his own compensation. Based on the evaluation of management's suggestions, the Compensation Committee then makes formal recommendations regarding executive compensation

decisions to the full Board of Directors. In making these recommendations, the Compensation Committee does not delegate any of its functions to others.

Our Compensation Committee has retained independent compensation consultants to advise on selected aspects of executive and Board compensation as follows:

- In 2007, Syzygy Consulting Group was retained to make recommendations regarding equity awards to Dr. Charles Link, who was then serving as our Chief Executive Officer, and Dr. Vahanian, who was then serving as our Chief Medical and Operating Officer, and to provide recommendations concerning Board compensation. The consultant's report was based on 34 United States-based life sciences and biotechnology companies that were managed by founders and had financing histories and valuations deemed similar to the company.
- In 2009, our Compensation Committee retained two compensation consultants, Syzygy Consulting Group and Radford, to provide recommendations on all aspects of executive compensation. The Syzygy report was based on a proprietary database of 160 private life sciences and biotechnology-related companies and its Pre-IPO and Private Technology Company Total Compensation Survey that covered compensation practices at 341 private companies. From those databases, Syzygy identified a group of similarly-situated, founder-managed companies based on cumulative capital raised and valuation. The Radford analysis was based on the 2009 Radford Global Life Sciences Pre-IPO Survey. These reports covered both the Company and our subsidiary BioProtection Systems Corporation, or BPS.
- In 2010, our Compensation Committee retained Syzygy Consulting Group to provide recommendations regarding the establishment and size of initial share reserves for an Employee Stock Purchase Plan and Non-Employee Directors' Stock Award Plan, and the addition of an "evergreen" provision to our 2009 Equity Incentive Plan. The Syzygy report was based on an analysis of the following 34 public biotechnology companies that were considered to be similar to us with respect to market capitalization:

  - Alnylam Pharmaceuticals, Inc.
  - Ariad Pharmaceuticals Inc.
  - Array BioPharma, Inc.
  - AVEO Pharmaceuticals, Inc.
  - BioCryst Pharmaceuticals, Inc.
  - BioTime, Inc.
  - Cadence Pharmaceuticals Inc.
  - Cell Therapeutics, Inc.
  - Chelsea Therapeutics International Ltd.
  - Clinical Data, Inc.
  - Codexis, Inc.
  - Corcept Therapeutics Inc.
  - Cornerstone Therapeutics Inc.
  - Cytokinetics Inc.
  - Cytori Therapeutics, Inc.
  - Dyax Corp.
  - Exact Sciences Corporation
  - Exelixis, Inc.
  - Idenix Pharmaceuticals Inc.
  - Immunogen Inc.
  - Jazz Pharmaceuticals, Inc.
  - Ligand Pharmaceuticals Inc.
  - Medivation, Inc.
  - Nabi Biopharmaceuticals
  - Neurocrine Biosciences Inc.
  - Novavax, Inc.
  - NPS Pharmaceuticals, Inc.
  - Obagi Medical Products, Inc.
  - Optimer Pharmaceuticals, Inc.
  - Osiris Therapeutics, Inc.
  - Sequenom Inc.
  - Vanda Pharmaceuticals, Inc.
  - Xenoport, Inc.
  - ZIOPHARM Oncology, Inc.

- In 2011, our Compensation Committee retained Radford to conduct a competitive review of the executive and director compensation programs. In addition to specific peer company data, the Radford analysis was based on the 2010 Radford Global Life Sciences Survey as well as the 2010 Radford Global Life Sciences Pre-IPO Survey.

In addition to relying on the consultants' reports, the committee members also have relied on the Ernst & Young 2008, 2009, and 2010 Compensation and Entrepreneurship Report in Life Sciences and on their own experience and observations in the marketplace in assessing and making recommendations regarding executive compensation. Our Board of Directors evaluates the recommendations from the Compensation Committee and makes final decisions regarding executive compensation.

Our Compensation Committee consists solely of directors who are "outside directors" for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and "non-employee directors" for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended.

Prior to our pending acquisition of the minority interest in our subsidiary BPS, it had its own compensation committee, consisting of Dr. Raffin and Mr. Talarico, who are also directors of the Company, and Mr. Steve Stahley, who is not a director, officer, employee or affiliate of the Company. Dr. Charles Link, our Chief Executive Officer, and Dr. Vahanian, our President and Chief Medical Officer have equity ownership positions in BPS. Neither Dr. Link nor Dr. Vahanian receives any salary from BPS. In September 2006, Drs. Link and Vahanian delivered notes to BPS in the principal amounts of $75,000 and $20,000, respectively, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation—Indebtedness of Management and Related Agreements."

Basis for Historical and Future Compensation Policies and Decisions

We use a mix of short-term compensation, consisting of base salaries and cash incentive bonuses, and long-term compensation, consisting of equity incentive compensation, to provide a total compensation structure that is designed to achieve our corporate objectives.

In arriving at the amount and types of initial compensation for each of our named executive officers, we consider the following factors:

- the individual's particular background and circumstances, including prior relevant work experience and compensation paid prior to joining us;
- the individual's role with us and the compensation paid to similar persons in the similarly situated companies represented in the compensation data that we review;
- the demand for people with the individual's specific expertise and experience;
- performance goals and other expectations for the individual's position;
- comparison to other executives within the Company having similar levels of expertise and experience; and
- recommendations from our compensation consultants.

We annually re-assess the compensation of our named executive officers and determine whether any adjustments should be made. In determining whether to adjust the compensation of any of our named executive officers, we generally take into account the following factors:

- our understanding of compensation generally paid by similarly situated companies to their executives with similar roles and responsibilities;
- formal market data regarding base salary, cash incentives and equity compensation from surveys conducted by our compensation consultants of biopharmaceutical and biotechnology companies, as well as the Ernst & Young report cited above;
- the roles and responsibilities of our executives, including any increases or decreases in responsibilities; and
- the contributions and performance of each named executive officer.

Elements of our Executive Compensation Program

General. Our executive compensation program consists of four principal components: base salary, performance-based cash bonus payments, long-term incentive compensation in the form of equity-based awards and severance and change-in-control benefits. Each component of our executive compensation program is designed to address specific compensation objectives. The Compensation Committee has not

established any formal policies or guidelines for allocating compensation between the components, although it seeks to maintain an appropriate balance between fixed compensation, in the form of base salary, and performance-based compensation, in the form of cash bonuses and long-term incentive compensation. As a general matter, our executive officers are also eligible to participate, on the same basis as other employees, in our 401(k) plan and our other benefit programs generally available to all employees, and with limited exceptions relating to the relocation of executive officers, we do not provide perquisites or benefits for our named executive officers on a basis that is different from other eligible employees.

We view each of the elements of our compensation program as related but distinct. Our decisions about each individual element generally do not affect the decisions we make about other elements. For example, we do not believe that significant compensation derived from one element of compensation, such as equity appreciation, should adversely affect compensation from other elements, such as salary or bonus.

Base Salary. Base salary is the primary fixed component of our executive compensation program. We use base salary to compensate executives for services rendered during the calendar year, and to ensure that we remain competitive in attracting and retaining executive talent.

Upon joining the Company, each of our executive officers received an offer letter that provided for an initial base salary. These initial salaries are the product of negotiation with the executive, but we generally seek to establish salaries that we believe are commensurate with the salaries paid to industry peers with comparable qualifications, experience, responsibilities and performance at similar companies. In addition to the Radford and Syzygy reports in 2009, we reviewed the Ernst & Young reports cited above. Our Compensation Committee has also relied on its members' collective experience in the marketplace for determining what they believe to be the market rate of salaries for executives of comparable companies.

Shortly before the end of each calendar year, we review company and individual performance to, among other things, determine whether adjustments in base salary are necessary or appropriate. In establishing the 2009 and 2010 base salaries of our executive officers, our Compensation Committee and Board of Directors took into account a number of factors, including the executive's seniority, position, functional role and level of responsibility and individual performance during the previous year. The Compensation Committee and Board of Directors then reviewed these factors with reference to the compensation reports and recommendations from Syzygy and Radford to establish compensation for each executive that was in line with similarly positioned executives at comparable companies.

Named Executive Officer	2009 Base Salary ($)	2010 Base Salary ($)	2011 Base Salary ($)
Charles J. Link, Jr., M.D.	354,895	440,682	485,000
Nicholas N. Vahanian, M.D.	256,316	312,322	343,600
Gordon H. Link, Jr.	228,375	239,794	263,800
Kenneth Lynn	231,750	243,338	255,500
W. Jay Ramsey, M.D., Ph.D.	162,225	240,000	255,000

For 2009, base salaries increased by 3% from 2008 levels for Dr. Charles Link, Dr. Vahanian, Mr. Lynn and Dr. Ramsey, and increased by 1.5% for Mr. Gordon Link. For 2010, the Compensation Committee and Board of Directors approved increases in total cash compensation for Dr. Charles Link and Dr. Vahanian of 24% and 22%, respectively. These increases were intended to provide for total cash compensation for Drs. Link and Vahanian at approximately the 75th percentile of the total cash compensation determined in the Syzygy report for similarly positioned executives in light of the progress of the Company and the increasing likelihood of an initial public offering of the Company's securities. The Compensation Committee and Board of Directors selected the 75th percentile as the benchmark for Dr. Link's and Dr. Vahanian's total compensation in recognition of their dual business and scientific roles, Dr. Link as Chief Executive Officer and Chief Scientific Officer and Dr. Vahanian as President and Chief Medical Officer. As such, they are responsible for developing both our business strategy and our scientific strategy, providing leadership for our business, scientific and clinical activities, and continuing to enhance

our intellectual property position. Similarly, for 2010, the Compensation Committee and Board of Directors approved increases in base salaries for Mr. Gordon Link, Mr. Lynn and Dr. Ramsey of 5%, 5% and 48%, respectively. These increases were intended to result in base salaries at approximately the 50th percentile of the base salaries determined in the Syzygy report for similarly positioned executives at comparable biotechnology companies per the Syzygy report in light of the Company's progress and the increasing likelihood of an initial public offering. Dr. Ramsey's increased base salary in 2010 also reflected his promotion to an executive of the Company in 2010. For 2011, the Compensation Committee and the Board of Directors approved increases in cash compensation for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey of 10.1%, 10%, 10%, 5% and 6.3%, respectively. These increases were based on the Radford report on executive and board compensation and are designed to more closely align our compensation practices with practices of companies similar to us as we become a public company.

We will continue to review base salaries of our executive officers on an annual basis and make adjustments to reflect individual performance-based factors, as well as our financial status. Historically, we have not applied, nor do we intend to apply, specific formulas to determine base salary increases.

Performance-Based Cash Bonuses. Our performance-based cash bonus program is designed to promote the interests of the Company and its stockholders by providing executive officers with the opportunity to earn annual cash bonuses based upon the achievement of pre-specified corporate and individual performance objectives, and to assist the Company in attracting and retaining executive talent.

Our annual cash bonus amounts are recommended by our Compensation Committee and approved by our Board, and these bonuses are ordinarily paid in a single installment in the first quarter of each year for performance in the prior year. Each executive officer is eligible for a discretionary annual cash incentive payment up to a specified percentage of the executive officer's salary. The Board of Directors sets these target percentages at levels that, upon achievement of the target percentage, are likely to result in cash bonus payments that the Board believes to be approximately the level paid to high-performing executives of comparable companies in the biopharmaceutical industry.

At the end of each year, our Chief Executive Officer develops bonus recommendations for each of our executive officers, based on the company's corporate accomplishments and the individual's performance and contributions to those accomplishments during the year. These recommendations are subjective determinations which may vary, from time to time, depending on our overall strategic objectives and the job responsibilities of each executive officer, but relate generally to factors such as development and progression of our existing product candidates, achievement of clinical and regulatory milestones, operational goals such as the expansion of our manufacturing capabilities, and financial factors such as raising and maintaining capital. However, these recommendations may be more or less than the established target percentages for the executive officers, depending on individual and corporate performance, as well as our financial position. The Compensation Committee assesses the bonuses recommended by management and makes its bonus recommendations to the full Board of Directors. Based on its consideration of the recommendations of the Compensation Committee, the full Board then makes a final decision regarding cash bonus payments, if any, for the year. Whether or not a cash bonus is paid for any year is solely within the discretion of the Board.

For 2009, based upon recommendations of the Compensation Committee, the Board of Directors established target bonus amounts for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey equal to 50%, 40%, 25%, 20% and 15% of their 2010 base salaries. As a basis for these performance bonuses, the Compensation Committee established corporate and individual performance objectives in January 2009, which were communicated to the named executive officers at that time. The corporate goals for the year included:

- receiving approval from the FDA to initiate our Phase 3 trial for HyperAcute Pancreas;
- developing Phase 2 clinical trial plans for D-1MT; and

- raising additional funding

Dr. Charles Link's performance goals for 2009 included leading the Company through the significant corporate developments referenced above. Dr. Vahanian's performance goals for 2009 included his role in running our day-to-day operations, including the achievements referenced above. Mr. Gordon Link's performance goals for 2009 included his primary responsibility, as our principal financial and accounting officer, for our Series C and Series D preferred stock financings that closed in 2009. Mr. Lynn's performance goals for 2009 included his role in establishing third party relationships and presenting our Company to outside companies for potential future collaborations. Dr. Ramsey's performance goals for 2009 included his role in regulatory and compliance accomplishments concerning clinical trials, manufacturing and quality assurance.

The Board determined that each of the 2009 corporate performance goals had been met or exceeded. The Compensation Committee determined that Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey had all met their individual 2009 performance goals. Taking all corporate and personal achievements into consideration, the Compensation Committee, in its discretion, made bonus recommendations for each executive officer in December 2009 and the Board of Directors adopted those bonus recommendations. The bonuses paid to Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey were equal to 50%, 40%, 25%, 20%, and 15% of their 2010 base salaries, respectively.

For 2010, based upon recommendations of the Compensation Committee, the Board of Directors established target bonus amounts for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey equal to 50%, 35%, 25%, 40% and 25% of their 2010 base salaries. The Compensation Committee also established corporate and individual performance objectives in June 2010, which were communicated to the named executive officers at that time. The corporate goals for the year included:

- initiating a Phase 3 clinical trial for HyperAcute Pancreas and meeting specific targets for patient enrollment and number of clinical centers;
- initiating a Phase 1B/2 clinical trial for D-1MT; and
- raising additional funding.

Each officer's individual goals consisted of one or more corporate goals and, in most cases, separate individual goals. Dr. Charles Link's performance goals for 2010 were the foregoing corporate goals. Dr. Vahanian's performance goals for 2010 included the corporate goals pertaining to the HyperAcute Pancreas and D-1MT trials and design of a HyperAcute Lung clinical study. Mr. Gordon Link's performance goals for 2010 included the corporate goal with respect to financing, raising additional funding and preparation for this offering. Mr. Lynn's performance goals for 2010 included the corporate goal with respect to financing, progress towards strategic third-party partnerships, and establishing an intellectual property committee. Dr. Ramsey's performance goals for 2010 included the corporate goal with respect to HyperAcute Pancreas trial, obtaining Orphan Drug and Fast Track approvals for HyperAcute Pancreas, validating the new HyperAcute immunotherapy production facility and initiating production of HyperAcute immunotherapy product candidates in that facility.

The Board determined that each of the 2010 corporate performance goals had been met or exceeded. The Compensation Committee determined that Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link and Dr. Ramsey had all met their individual 2010 performance goals. The Compensation Committee determined that Mr. Lynn achieved substantially all of his stated objectives, but did not fully satisfy his individual performance goals with respect to progress towards strategic partnerships. Taking all corporate and personal achievements into consideration, the Compensation Committee, in its discretion, made bonus recommendations for each executive officer in December 2010 and the Board of Directors adopted those bonus recommendations. The bonuses paid to Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey were equal to 50%, 35%, 25%, 28%, and 25% of their 2010 base salaries, respectively.

For 2011, based upon recommendations of the Compensation Committee, the Board of Directors established target bonus amounts for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey equal to 50%, 40%, 30%, 30% and 30% of their 2011 base salaries. The Compensation Committee also established corporate and individual performance objectives in January 2011, which were communicated to the named executive officers at that time. The corporate goals for the year include:

- meeting specific targets for patient enrollment in HyperAcute Pancreas Phase III; and
- raising additional funding.

Each officer's individual goals consist of one or more corporate goals and, in most cases, separate individual goals. Dr. Charles Link's performance goals for 2011 are the foregoing corporate goals as well as meeting specific targets for patient enrollment for HyperAcute Lung Phase 2B study. Dr. Vahanian's performance goals for 2011 include the corporate goal pertaining to HyperAcute Pancreas, HyperAcute Lung Phase 2B and oversight of vaccine manufacturing for HyperAcute Pancreas. Mr. Gordon Link's performance goals for 2011 include the corporate goal with respect to financing, raising additional funding and SEC reporting. Mr. Lynn's performance goals for 2011 include the corporate goal with respect to financing and progress towards strategic third-party partnerships. Dr. Ramsey's performance goals for 2011 include initiating a validation master plan for the HyperAcute product line and submitting new IND(s) covering additional HyperAcute or IDO pathway inhibitor product candidates.

The Board will make determinations on 2011 corporate and individual performance goals after the conclusion of 2011.

We have not determined whether we would seek to recover cash bonus payments paid to our executive officers if the performance objectives that led to the determination of such payments were to be restated or found not to have been met to the extent that we originally believed.

In addition, in 2010, BPS paid Dr. Charles Link and Dr. Vahanian discretionary performance based bonuses in aggregate amounts of $65,000 and $30,000, respectively, which were approved by the BPS Board of Directors. Of these amounts, $15,000 was paid to each executive in connection with BPS's securing a research and development contract with the U.S. Department of Defense relating to the study of a-Gal adjuvant technology for the biodefense field and the remainder was paid in connection with BPS's securing licensing agreement with Her Majesty the Queen in Right of Canada relating to rVSV. These bonuses were approved after those contracts were awarded and were not a result of any pre-defined performance goals for BPS.

Equity Compensation. Equity incentives represent the largest at-risk component of our executive compensation program. Our equity incentives are designed to align the interests of our executive officers with those of our stockholders by creating an incentive for our executive officers to maximize stockholder value and to remain employed with us despite a competitive labor market through the grant of time-vested stock options.

Initial option grants to our executive officers are generally set forth in an offer letter. These initial option grants are the product of negotiation with the executive, but we generally seek to establish equity ownership levels that we believe are commensurate with the equity stakes of industry peers with comparable qualifications, experience, responsibilities and performance at similar companies. In addition, as part of our annual compensation review process, we provide subsequent option grants to those executive officers determined to be performing well.

In May 2009, we granted Dr. Charles Link a stock option for 1,538,275 shares and Dr. Vahanian a stock option for 695,725 shares, each at an exercise price of $1.00 per share. These options vest over five years beginning on June 29, 2007, and expire on December 13, 2017. These grants had been initially approved by the Compensation Committee and the Board in June 2007, but the Company did not have sufficient shares authorized under its 2000 Equity Incentive Plan at that time. In 2009 the Company adopted the 2009 Equity Incentive Plan and these options were approved and granted by the Board under

that plan. In December 2009, we granted Dr. Charles Link a stock option for 900,000 shares of common stock, and Dr. Vahanian a stock option for 800,000 shares of common stock, each at an exercise price of $1.41 per share. These options vest as to 25% on the first anniversary of the date of grant and as to the remainder in equal monthly increments over the following 36 months. These options expire December 3, 2019. In March 2010, we granted Dr. Vahanian a stock option for 400,000 shares, Mr. Gordon Link a stock option for 10,000 shares and Dr. Ramsey a stock option for 108,000 shares, each at an exercise price of $1.46 per share. These options vest as to 25% on December 4, 2010 for Dr. Vahanian and March 3, 2011 for Mr. Gordon Link and Dr. Ramsey, and as to the remainder in equal monthly increments over the following 36 months. These options expire on March 2, 2020. All of these grants were recommended to the Board by our Compensation Committee, which considered the advice of our independent compensation consultants regarding executive equity ownership. Our independent compensation consultants compared our executives' ownership positions with other similarly-situated biopharmaceutical companies and, in recommending these grants, the Compensation Committee considered the executives' roles and responsibilities within the company, and their ownership positions in relation to similarly-situated companies as defined by our Compensation Committee. The December 2009 grants to Dr. Link and Dr. Vahanian and March 2010 grant to Dr. Vahanian resulted in equity ownership percentages above the median of the companies in the group of companies analyzed by our compensation consultant. The Compensation Committee and Board approved these grants in recognition of the leadership of Dr. Link and Dr. Vahanian in achieving company goals and raising capital.

In April 2011, we approved stock options for our executive officers, reflecting the Compensation Committee's recommendations based on the "mid" tier from the April 2011 Radford report. These stock option grants were approved by the board for Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey in the amounts of 200,000 shares, 90,000 shares, 147,500 shares, 40,000 shares and 40,000 shares, respectively. These options vest as to 25% on the first anniversary of the date of grant and as to the remainder in equal monthly increments over the following 36 months. These stock option grants are to become effective upon pricing of the Company's proposed initial public offering of Common Stock registered under the Securities Act of 1933, provided that the initial public offering is completed by December 31, 2011, and the exercise price will be the same as the the "price to public" in the initial public offering in the event the Company completes an initial public offering by such date. If the initial public offering is not completed by such date, such options shall have an exercise price equal to the fair market value of one share of Common Stock as of December 31, 2011, as determined by a valuation report of The Mentor Group, the Company's independent valuation consultant. These options will expire on April 13, 2021.

Severance and Change of Control Benefits. We enter into employment agreements with our executives in select cases, generally when it is necessary to secure the services of a newly hired executive. We entered into employment agreements with each of Dr. Charles Link, Dr. Vahanian, Mr. Gordon Link, Mr. Lynn and Dr. Ramsey, as well as certain other officers. These agreements provide for severance compensation to be paid if the officers are terminated under certain conditions, such as in connection with a change-in-control of the Company or a termination without cause by us, each as defined in the agreements. The severance compensation payable under the employment agreements are described in more detail beginning on page 147 of this prospectus under the heading "Potential Payments Upon Termination or Change in Control."

In our experience, post-termination protection for executive officers is common among our peer group, and the Compensation Committee believes that providing this protection is essential to our ability to attract and retain talented executives capable of providing the leadership, vision and execution necessary to achieve our business objectives. In addition, the employment agreements and the related post-termination compensation provisions are designed to meet the following objectives:

- *Change in control:* As part of our normal course of business, we engage in discussions with other pharmaceutical companies about possible collaborations, licensing and/or other ways in which the companies may work together to further our respective long-term objectives. In addition, many

larger established pharmaceutical companies consider companies at similar stages of development to ours as potential acquisition targets. In certain scenarios, the potential for a merger or being acquired may be in the best interests of our stockholders. We provide post-termination compensation if an officer is terminated as a result of a change-in-control transaction to promote the ability of our officers to act in the best interests of our stockholders even though they could be terminated as a result of the transaction.

- *Termination Without Cause:* In certain instances, if we terminate the employment of an officer "without cause" or the officer resigns for "good reason," each as defined in the applicable agreement, we are obligated to pay the officers certain severance benefits under their employment agreements. We believe this is appropriate because the terminated officer is bound by confidentiality and non-competition provisions covering one year after termination and because we and the officer have a mutually agreed-to severance package that is in place prior to any termination event. This provides us with more flexibility to make a change in senior management if such a change is in our and our stockholders' best interest.

401(k) Plan. Our employees, including our executive officers, are eligible to participate in our 401(k) plan. Our 401(k) plan is intended to qualify as a tax qualified plan under Section 401 of the Code. Our 401(k) plan provides that each participant may contribute a portion of his or her pretax compensation, up to a statutory limit, which for most employees was $16,500 in 2009 and 2010, with a larger "catch up" limit for older employees. Employee contributions are held and invested by the plan's trustee. We provide a contribution of 3% of each participant's salary with a possibility of an additional discretionary contributions.

Other Benefits and Perquisites. We pay a portion of the premiums for medical insurance, dental insurance, life insurance and accidental death and dismemberment insurance benefits to all full-time employees, including our executive officers. These benefits are available to all employees, subject to applicable laws. Our executive officers have not historically received perquisites valued in aggregate at more than $10,000 per year per person, with the exception of Dr. Charles Link, who received perquisites totalling $18,443 in 2009 and $14,846 in 2010. The Compensation Committee will evaluate perquisites annually as an element of overall compensation. From time to time, we have provided relocation expenses in connection with the relocation of executive officers to the geographic area of our corporate headquarters in Ames, Iowa. We intend to continue to provide relocation expenses in the future, as necessary, to obtain the services of qualified individuals.

Executive Loans. Between September 2006 and October 2010, the Company and its subsidiary BPS extended loans to Dr. Charles Link, Dr. Vahanian and Mr. Gordon Link. The loans made by the Company were extended to Dr. Charles Link and Dr. Vahanian for personal purposes and to Mr. Gordon Link to facilitate purchase of a home in Ankeny, Iowa. In light of the Company's planned initial public offering, and in accordance with the recommendation of its compensation consultants, the Company's Compensation Committee recommended and the Company's Board agreed in May 2010 to forgive Dr. Charles Link's and Dr. Vahanian's loans and pay a bonus equal to the resulting tax liability in exchange for the executives' agreement to increase the exercise price of certain outstanding stock options. As of July 2, 2010, the aggregate exercise price of these options was increased by an amount equal to the principal and accrued interest on the loans forgiven plus the bonuses paid to cover the resulting tax liability. Mr. Gordon Link repaid his loan in full on May 11, 2010.

In September 2006, Dr. Charles Link and Dr. Vahanian delivered notes to BPS in the principal amounts of $75,000 and $20,000, respectively, bearing interest at 5.01% per annum, in order to purchase their shares of BPS Series B common stock under stock options. As of November 17, 2010, Dr. Link and Dr. Vahanian had repaid the remaining principal and interest owed under the notes. For a more detailed description of these loans, see "Executive and Director Compensation—Indebtedness of Management and Related Agreements." No loans to executives of the company or BPS are currently outstanding and it is the policy of the Company and BPS not to extend loans to officers or directors in the future.

Other Compensation. We intend to continue to maintain the current benefits for our executive officers, which are also available to all of our other employees; however, our Compensation Committee, in its discretion, may in the future revise, amend or add to the benefits of any executive officer if it deems it advisable.

Federal Tax Considerations Under Sections 162(m) and 409A

Section 162(m) of the Code limits our deduction for federal income tax purposes to not more than $1 million of compensation paid to specified executive officers in a calendar year. Compensation above $1 million may be deducted if it is performance-based compensation within the meaning of Section 162(m). Our Compensation Committee has not yet established a policy for determining which forms of incentive compensation awarded to our executive officers will be designed to qualify as performance-based compensation. To maintain flexibility in compensating our executive officers in a manner designed to promote our objectives, our Compensation Committee has not adopted a policy that requires all compensation to be deductible. However, the committee intends to evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant, and the Compensation Committee intends to provide future compensation in a manner consistent with our best interests and those of our stockholders.

Section 409A of the Code addresses the tax treatment of nonqualified deferred compensation benefits and provides for significant taxes and penalties in the case of payment of nonqualified deferred compensation. We currently intend to structure our executive compensation programs to avoid triggering these taxes and penalties under Section 409A.

Accounting Considerations

Under ASC 718, we are required to estimate and record an expense for each award of equity compensation, including stock options, over the vesting period of the award. Our Board of Directors has determined to retain for the foreseeable future our stock option program as the sole component of its long-term compensation program, and, therefore, to record this expense on an ongoing basis according to ASC 718. Our Compensation Committee may in the future consider the grant of restricted stock or other equity-based awards to our executive officers in lieu of stock option grants, in light of the accounting impact of ASC 718 with respect to stock option grants.

Compensation Policies and Practices as They Relate to Risk Management

The Company believes that risks arising from its compensation policies and practices for its employees are not reasonably likely to have a material adverse effect on the Company. In addition, the Compensation Committee believes that the mix and design of the elements of executive compensation do not encourage management to assume excessive risks.

The Compensation Committee has reviewed the elements of executive compensation to determine whether any portion of executive compensation encouraged excessive risk taking and concluded:

- significant weighting towards long-term incentive compensation discourages short-term risk taking, including use of multi-year vesting for equity awards which compromise the majority of compensation awards;
- goals are set to focus mainly on key events related to the overall success of the Company's product development rather than individual components;
- vesting conditions imposed on option awards after performance targets are reached discourage short-term risk taking;
- incentive awards are benchmarked to calculate reasonable overall compensation; and

- as a biopharmaceutical business, the Company does not face the same level of risks associated with compensation for employees at financial services companies (traders and instruments with a high degree of risk).

Furthermore, as described above in "Compensation Discussion and Analysis," compensation decisions include subjective considerations, which help to constrain the influence of formulae or objective factors on excessive risk taking.

Summary Compensation Table

The following table sets forth information regarding compensation earned during the years ended December 31, 2010 and 2009, by our principal executive officer, our principal financial officer and our three other most highly compensated executive officers serving as executive officers at December 31, 2010 whose total compensation exceeded $100,000 for the year ended December 31, 2009. We refer to these persons as our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus(1) ($)	Option Awards(2) ($)	All Other Compensation ($)	Total ($)
Charles J. Link, Jr., M.D.	2010	440,682	285,341(4)	—	643,609(5)	1,369,632
Chairman of the Board and Chief Executive and Scientific Officer	2009	354,895	298,490(6)	307,655	57,073(7)	1,018,113
Nicholas N. Vahanian, M.D.	2010	312,322	139,313(8)	—	78,571(9)	530,206
President and Chief Medical Officer	2009	256,316	179,966(10)	139,145	34,496	609,923
Gordon H. Link, Jr.	2010	239,794	59,949	—	23,345(11)	323,088
Chief Financial Officer	2009	228,375	59,948	52,500	13,294(12)	354,117
Kenneth Lynn	2010	243,338	68,135	—	13,190	324,663
Executive Vice President of Business Development	2009	231,750	48,668	52,500	14,350	347,268
W. Jay Ramsey, M.D., Ph.D.	2010	240,000	60,000	—	12,827	312,827
Quality Assurance Officer	2009	162,225	36,000	8,400	13,597	220,222

(1) Performance bonuses are based on a percentage of 2010 base salary. For 2010 and 2009, Dr. Charles Link was awarded cash performance bonuses of 50% of his 2010 base salary, which was $440,682. For 2010 and 2009, Dr. Vahanian was awarded cash performance bonuses of 35% and 40%, respectively, of his 2010 base salary, which was $312,332. For 2010 and 2009, Mr. Gordon Link was awarded cash performance bonuses of 25% of his 2010 base salary, which was $239,794. For 2010 and 2009, Mr. Lynn was awarded cash performance bonuses of 28% and 20%, respectively, of his 2010 base salary, which was $243,338. For 2010 and 2009, Dr. Ramsey was awarded cash performance bonuses of 25% and 15%, respectively, of his 2010 base salary, which was $240,000.

(2) The assumptions we used in valuing options are described under the caption "Stock Option Valuation" in note 2(n) to our financial statements included in this prospectus. This column reflects compensation expense that would be recorded under ASC 718 as stock-based compensation in our financial statements for the indicated year in connection with options we granted in the indicated year and in prior years, adjusted to disregard the effects of any estimate of forfeitures related to service-based vesting, if we had adopted the modified-prospective transition method of ASC 718. As a result, unlike our financial statements for the indicated year, the amounts in the table include values associated with stock options that were granted prior to January 1, 2006 and that had not fully vested prior to the indicated year, and assume that the executive will perform the requisite service for the award to vest.

(3) Unless otherwise indicated, amounts in this column represent Company contributions under our 401(k) plan.

(4) Amount includes the performance bonus discussed in footnote (1) and bonuses of $50,000 and $15,000 received by Dr. Charles Link from BPS.

(5) Amount includes: (i) a $29,850 contribution under the Company's 401(k) plan; (ii) $14,846 in perquisites and personal benefits received by Dr. Charles Link that we reimbursed or paid on his behalf in 2010, including insurance, memberships, a medical license and various other Company provided benefits; (iii) $43,517 in loan and accrued interest forgiveness by BPS; and (iv) $555,396 in loan and accrued interest forgiveness by the Company and a tax gross-up, which was offset by increasing the exercise price of options to purchase 555,396 shares of common stock held by Dr. Link from $1.00 per share to $2.00 per share, as described in more detail on page 160 of this prospectus.

(6) Amount includes the performance bonus discussed in footnote (1) and a $78,149 bonus received by Dr. Charles Link from the Company.

(7) Amount includes (i) a $38,630 contribution under the Company's 401(k) plan and (ii) $18,443 in perquisites and personal benefits received by Dr. Charles Link that we reimbursed or paid on his behalf in 2009, including insurance, memberships, a medical license and various other Company provided benefits.

(8) Amount includes the performance bonus discussed in footnote (1) and two $15,000 bonuses received by Dr. Vahanian from BPS.

(9) Amount includes: (i) a $19,600 contribution under the Company's 401(k) plan; (ii) $10,357 of loan interest forgiveness; (iii) $11,604 in loan and accrued interest forgiveness by BPS; and (iv) $37,010 in loan and accrued interest forgiveness by the Company and a tax gross-up, which was offset by increasing the exercise price of options to purchase 37,010 shares of common stock held by Dr. Vahanian from $1.00 per share to $2.00 per share, as described in more detail on page 160 of this prospectus.

(10) Amount includes the performance bonus discussed in footnote (1) and a $55,037 bonus received by Dr. Vahanian from the Company.

(11) Amount includes (i) a $13,345 contribution under the Company's 401(k) plan, of which $5,995 is non-vested and subject to Mr. Link's continued service with the Company through 2011, and (ii) $10,000 in loan and accrued interest forgiveness by the Company.

(12) Amount represents a $13,294 contribution under the Company's 401(k) plan, of which $7,000 is non-vested and subject to Mr. Link's continued service with the Company through 2011.

2010 Grants of Plan-Based Awards

The following table lists grants of plan-based awards made to our named executive officers in 2010:

Grants Of Plan-Based Awards

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Fair Value of Shares Available Under Grant
Nicholas N. Vahanian	3/3/2010	400,000(1)	$ 1.46	$ 584,000
Gordon H. Link, Jr.	3/3/2010	10,000(2)	$ 1.46	$ 14,600
W. Jay Ramsey	3/3/2010	108,000(2)	$ 1.46	$ 157,680

(1) The vesting commencement date of these options was December 4, 2009. See "Executive and Director Compensation—Elements of our Executive Compensation Program—Equity Compensation" for further discussion of this option grant.

(2) The vesting commencement date of these options was March 3, 2010. See "Executive and Director Compensation—Elements of our Executive Compensation Program—Equity Compensation" for further discussion of this option grant.

2011 Grants of Plan-Based Awards

Anticipated Grants of Plan-Based Awards

Name	Approval Date	All other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)(1)	Fair Value of Shares Available Under Grant(2)
Charles J. Link, Jr., M.D.	4/14/2011	200,000	—	—
Nicholas N. Vahanian, M.D.	4/14/2011	90,000	—	—
Gordon H. Link, Jr.	4/14/2011	147,500	—	—
Kenneth Lynn	4/14/2011	40,000	—	—
W. Jay Ramsey, M.D., Ph.D.	4/14/2011	40,000	—	—

(1) These stock option grants are to become effective upon pricing of the Company's proposed initial public offering of Common Stock registered under the Securities Act of 1933, provided that the initial public offering is completed by December 31, 2011, and the exercise price will be the same as the the "price to public" in the initial public offering in the event the Company completes an initial public offering by such date. If the initial public offering is not completed by such date, such options shall have an exercise price equal to the fair market value of one share of Common Stock as of December 31, 2011, as determined by a valuation report of The Mentor Group, the Company's independent valuation consultant.

(2) Cannot calculate due to unknown exercise price

Outstanding Equity Awards at June 30, 2011

The following table provides information about outstanding stock options held by each of our named executive officers at June 30, 2011. All of these options were granted under our 2000 Equity Incentive Plan. Our named executive officers did not hold any restricted stock or other stock awards at the end of 2010.

Name	Number of Shares Underlying Unexercised Options(1) (#) Exercisable	(#) Unexercisable(2)	Option Vesting Commencement Date	Option Exercise Price	Option Expiration Date
Charles J. Link, Jr., M.D.	786,303(4)(6)	196,576	6/1/2007	$ 1.00	5/12/2019
	444,316(4)(6)	111,080	6/1/2007	$ 2.00	5/12/2019
	337,500(3)	562,500	12/4/2009	$ 1.41	12/3/2019
	2,602(4)(8)	2,783	1/1/2009	$ 0.38	1/20/2019
Nicholas N. Vahanian, M.D.	5,000(5)	0	10/18/2002	$ 1.00	7/15/2018
	75,000(3)	0	10/18/2002	$ 1.00	7/15/2018
	526,972(4)(7)	131,743	6/1/2007	$ 1.00	5/12/2019
	29,608(4)(7)	7,402	6/1/2007	$ 2.00	5/12/2019
	300,000(3)	500,000	12/4/2009	$ 1.41	12/3/2019
	141,666(3)	258,334	12/4/2009	$ 1.46	12/3/2019
	2,602(4)(8)	2,783	1/1/2009	$ 0.38	1/20/2019
Gordon H. Link, Jr.	141,666(3)	58,334	8/4/2008	$ 1.00	8/5/2018
	10,000(5)	0	3/3/2010	$ 1.46	3/2/2020
	5,721(3)(8)	2,357	8/1/2008	$ 0.38	9/11/2018
Kenneth Lynn	175,000(3)	35,000	2/25/2008	$ 1.00	8/5/2018
	4,577(4)(8)	3,501	8/1/2008	$ 0.38	1/20/2019
W. Jay Ramsey, M.D., Ph.D.	32,000(4)	8,000	6/29/2007	$ 1.00	6/28/2017
	5,000(3)	0	10/18/2002	$ 1.00	7/15/2018
	5,000(3)	0	9/1/2004	$ 1.00	7/15/2018
	2,000(4)	0	4/4/2005	$ 1.00	7/15/2018
	33,750(3)	74,250	3/3/2010	$ 1.46	3/2/2020

(1) Unless otherwise indicated, these options have a 10-year term.

(2) This column shows options that were unvested as of June 30, 2011.

(3) These options vest over a four-year period, with 25% of the options vesting on the first anniversary of the vesting commencement date and the remaining 75% of the options vesting in equal monthly installments thereafter over the next three years, subject to the recipient's continued employment with the Company through such vesting dates.

(4) These options vest over a five-year period, with 20% of the options vesting on the first anniversary of the vesting commencement date and the remaining 80% of the options vesting in equal monthly installments thereafter over the next four years, subject to the recipient's continued employment with the Company through such vesting dates.

(5) These options and were fully vested as of the date of grant.

(6) Dr. Charles Link was granted a total option of 1,538,275 shares at $1.00 per shares, which was amended on July 1, 2010 and split into separate grants of 982,879 with a price of $1.00 and 555,396 with a price of $2.00.

(7) Dr. Nicholas Vahanian was granted a total option of 695,725 shares at $1.00 per shares, which was amended on July 1, 2010 and split into separate grants of 658,715 with a price of $1.00 and 37,010 with a price of $2.00

(8) This number represents outstanding stock options to purchase stock in the Company that were issued on January 7, 2011 in exchange for options to purchase stock in our subsidiary, BPS.

2010 Option Exercises and Stock Vested

The following table lists exercise of stock options during 2010 for each of the named executive officers:

Name	Option Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)
Nicholas N. Vahanian, M.D.	75,000	18,750
Gordon H. Link, Jr.	10,000	10,000

Employment Agreements

The Company has entered into employment agreements with each of the named executive officers. The material terms of the agreements are summarized below.

Employment Agreement with Dr. Charles Link

On December 6, 2010, the Company entered into an employment agreement with Dr. Charles Link in connection with his employment as Chief Executive Officer. Pursuant to the employment agreement, Dr. Link earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Link earns an annual base salary of $485,000. Dr. Link is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Link's target bonus is set at 50% of his annual base salary.

The employment agreement with Dr. Link also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Link or the Company at any time. However, if the Company terminates Dr. Link's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Link executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

The employment agreement with Dr. Link further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Link's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Link executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

Employment Agreement with Dr. Nicholas Vahanian

On November 22, 2010, the Company entered into an employment agreement with Dr. Nicholas Vahanian in connection with his employment as President and Chief Medical Officer. Pursuant to the employment agreement, Dr. Vahanian earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Vahanian earns an annual base salary of $343,600. Dr. Vahanian is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Vahanian's target bonus is set at 40% of his annual base salary.

The employment agreement with Dr. Vahanian also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Vahanian or the Company at any time. However,

if the Company terminates Dr. Vahanian's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Vahanian executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

The employment agreement with Dr. Vahanian further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Vahanian's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Vahanian executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

Employment Agreement with Mr. Gordon Link

On November 22, 2010, the Company entered into an employment agreement with Mr. Gordon Link in connection with his employment as Chief Financial Officer. Pursuant to the employment agreement, Mr. Link earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Mr. Link earns an annual base salary of $263,800. Mr. Link is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Mr. Link's target bonus is set at 30% of his annual base salary.

The employment agreement with Mr. Link also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Link or the Company at any time. However, if the Company terminates Mr. Link's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Mr. Link executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

The employment agreement with Mr. Link further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Link's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Mr. Link executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

Employment Agreement with Mr. Kenneth Lynn

On November 22, 2010, the Company entered into an employment agreement with Mr. Kenneth Lynn in connection with his employment as Executive Vice President, Business Development. Pursuant to the employment agreement, Mr. Lynn earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Mr. Lynn earns an annual base salary of $255,500. Mr. Lynn is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Mr. Lynn's target bonus is set at 30% of his annual base salary.

The employment agreement with Mr. Lynn also provides that his employment with the Company is at-will and may be altered or terminated by either Mr. Lynn or the Company at any time. However, if the Company terminates Mr. Lynn's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Mr. Lynn executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which

are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

The employment agreement with Mr. Lynn further provides that if the Company (or any surviving or acquiring corporation) terminates Mr. Lynn's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Mr. Lynn executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

Employment Agreement with Dr. W. Jay Ramsey

On November 22, 2010, the Company entered into an employment agreement with Dr. W. Jay Ramsey in connection with his employment as Quality Assurance and Quality Control Officer. Pursuant to the employment agreement, Dr. Ramsey earns an annual base salary, which is subject to annual review and adjustment by the Board of Directors. Currently, Dr. Ramsey earns an annual base salary of $255,000. Dr. Ramsey is also eligible to receive an annual performance bonus based on his achievement of certain milestones and performance objectives. Currently, Dr. Ramsey's target bonus is set at 30% of his annual base salary.

The employment agreement with Dr. Ramsey also provides that his employment with the Company is at-will and may be altered or terminated by either Dr. Ramsey or the Company at any time. However, if the Company terminates Dr. Ramsey's employment without just cause or if he resigns for good reason (other than in connection with a change-in-control of the Company), as long as Dr. Ramsey executes a general release in favor of the Company, he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

The employment agreement with Dr. Ramsey further provides that if the Company (or any surviving or acquiring corporation) terminates Dr. Ramsey's employment without just cause or if he resigns for good reason within one month prior to or 13 months following the effective date of a change-in-control of the Company, as long as Dr. Ramsey executes a general release in favor of the Company (or any surviving or acquiring corporation), he will be entitled to receive certain payments and other benefits, which are described in more detail under the heading "Potential Payments Upon Termination or Change in Control" beginning on page 147 of this prospectus.

Potential Payments Upon Termination or Change in Control

Under the terms of employment agreements with our named executive officers, if the Company terminates a named executive officer's employment for "cause" or a named executive officer resigns without "good reason," such named executive officer is entitled to the following: (i) any salary earned but unpaid prior to termination, (ii) any benefits accrued prior to termination, (iii) all accrued but unused vacation and (iv) any business expenses that were incurred but not reimbursed as of the date of termination (collectively, the "Accrued Obligations"). Following such termination, vesting of such named executive officer's then outstanding stock options shall cease on the date of such termination.

Under the terms of employment agreements with the named executive officers, if the Company terminates a named executive officer's employment without just cause or a named executive officer resigns with good reason (other than in connection with a change in control of the Company), and in each case such named executive officer signs a general release and written acknowledgment of his continuing obligations under his confidentiality and inventions assignment agreement with the Company, such named executive officer is entitled to the following: (i) payment of the Accrued Obligations; (ii) depending on the named executive officer and as described in the tables below, the equivalent of 24, 12 or 6 months of such

named executive officer's base salary as in effect immediately prior to the termination date, payable on the same basis and at the same time as previously paid and subject to employment tax withholdings and deductions; and (iii) depending on the named executive officer and as described in the tables below, payment of such named executive officer's COBRA premiums for 24, 12 or 6 months to be paid in order for such named executive officer to maintain medical insurance coverage that is substantially equivalent to that which such named executive officer received immediately prior to the termination payment of premiums for his group health insurance. In the event that such named executive officer breaches his confidentiality, non-compete or non-solicitation obligations under his confidentiality and inventions assignment agreement with the Company, the payments described above, except for the Accrued Obligations, shall cease, and the Company shall have no further obligations to such named executive officer with respect thereto. The Company's obligation to pay such named executive officer's COBRA premiums ceases upon such named executive officer's eligibility for comparable coverage provided by a new employer.

Under the terms of the employment agreements with the named executive officers, if the Company (or any surviving or acquiring corporation) terminates a named executive officer's employment without cause or a named executive officer resigns with good reason within one month prior to or 13 months following the effective date of a change in control of the Company (either constituting a "Change of Control Termination"), and in each case such named executive officer signs a general release and written acknowledgment of his continuing obligations under his confidentiality and inventions assignment agreement with the Company, such named executive officer is entitled to the following: (i) payment of the Accrued Obligations; (ii) depending on the named executive officer and as described in the tables below, the equivalent of 24, 12 or 6 months of such named executive officer's base salary as in effect immediately prior to the termination date, payable on the same basis and at the same time as previously paid and subject to employment tax withholdings and deductions; (iii) depending on the named executive officer and as described in the tables below, payment of such named executive officer's COBRA premiums for 24, 12 or 6 months to be paid in order for such named executive officer to maintain medical insurance coverage that is substantially equivalent to that which such named executive officer received immediately prior to the termination payment of premiums for his group health insurance; and (iv) the Company will vest 100% of the shares subject to such named executive officer's options and such vesting shall occur upon the occurrence of the change of control in the case of a Change of Control Termination occurring prior to the change in control or upon termination in the case of a Change of Control Termination occurring after the change of control. If a named executive officer breaches his confidentiality, non-compete or non-solicitation obligations under his confidentiality and inventions assignment agreement with the Company, the payments described above, except for the Accrued Obligations, shall cease, and the Company shall have no further obligations to such named executive officer with respect thereto. The Company's obligation to pay such named executive officer's COBRA premiums ceases upon such named executive officer's eligibility for comparable coverage provided by a new employer.

The following tables reflect the estimated potential payments that would be payable to each named executive officer upon a termination or change-in-control of the Company under the terms of his employment agreement. The amounts shown reflect only the additional payments or benefits that each named executive officer would have received upon the occurrence of the respective triggering events listed below; they do not include the value of payments or benefits that would have been earned, or any amounts associated with equity awards that would have vested, absent the triggering event. For purposes of

calculating the potential payments set forth in the tables below, we have assumed that (i) the date of termination was June 30, 2011 and (ii) the stock price was $4.77.

Charles J. Link, Jr., M.D.	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)
Cash Payments			
Cash Severance	$ —	$ 970,000(1)	$ 970,000(1)
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 2,951,000(2)
Benefits and Perquisites			
Accrued Obligations	$ 41,442(3)	$ 41,442(3)	$ 41,442(3)
Benefits Continuation	$ —	$ 22,934(4)	$ 22,934(4)
Total Payments Upon Termination	$ 41,442	$ 1,034,376	$ 3,985,376

(1) Amount represents 24 months of his base salary then in effect.

(2) Amount represents the in-the-money value of unvested NewLink stock options as of June 30, 2011, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at June 30, 2011" table set forth on page 144 of this prospectus.

(3) Amount represents (i) a $6,000 contribution under the Company's 401(k) plan and (ii) $35,442 in accrued vacation.

(4) Amount represents 24 months of COBRA premiums.

Nicholas N. Vahanian, M.D.	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)
Cash Payments			
Cash Severance	$ —	$ 343,600(1)	$ 343,600(1)
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 3,064,478(2)
Benefits and Perquisites			
Accrued Obligations	$ 34,803(3)	$ 34,803(3)	$ 34,803(3)
Benefits Continuation	$ —	$ 11,467(4)	$ 11,467(4)
Total Payments Upon Termination	$ 34,803	$ 389,870	$ 3,454,348

(1) Amount represents 12 months of his base salary then in effect.

(2) Amount represents the in-the-money value of unvested NewLink stock options as of June 30, 2011, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at June 30, 2011" table set forth on page 144 of this prospectus.

(3) Amount represents (i) a $12,000 contribution under the Company's 401(k) plan and (ii) $22,803 in accrued vacation.

(4) Amount represents 12 months of COBRA premiums.

Gordon H. Link, Jr.	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)
Cash Payments			
Cash Severance	$ —	$ 131,900(1)	$ 131,900(1)
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 230,266(2)
Benefits and Perquisites			
Accrued Obligations	$ 24,134(3)	$ 24,134(3)	$ 24,134(3)
Benefits Continuation	$ —	$ 5,734(4)	$ 5,734(4)
Total Payments Upon Termination	$ 24,134	$ 161,768	$ 392,034

(1) Amount represents six months of his base salary then in effect.

(2) Amount represents the in-the-money value of unvested NewLink stock options as of June 30, 2011, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at June 30, 2011" table set forth on page 144 of this prospectus.

(3) Amount represents (i) a $3,837 contribution under the Company's 401(k) plan and (ii) $20,297 in accrued vacation.

(4) Amount represents six months of COBRA premiums.

Kenneth Lynn	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)
Cash Payments			
Cash Severance	$ —	$ 127,750(1)	$ 127,750(1)
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 147,319(2)
Benefits and Perquisites			
Accrued Obligations	$ 15,728(3)	$ 15,728(3)	$ 15,728(3)
Benefits Continuation	$ —	$ 5,734(4)	$ 5,734(4)
Total Payments Upon Termination	$ 15,728	$ 149,212	$ 296,531

(1) Amount represents six months of his base salary then in effect.

(2) Amount represents the in-the-money value of unvested NewLink stock options as of June 30, 2011, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at June 30, 2011" table set forth on page 144 of this prospectus.

(3) Amount represents $15,728 in accrued vacation.

(4) Amount represents six months of COBRA premiums.

W. Jay Ramsey, M.D., Ph.D.	Termination For Just Cause or Resignation Without Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason Termination	Termination Without Just Cause or Resignation With Good Reason (in connection with a Change in Control)
Cash Payments			
Cash Severance	$ —	$ 127,500(1)	$ 127,500(1)
Long-Term Incentives			
Stock Options (Unvested and Accelerated)	$ —	$ —	$ 275,928(2)
Benefits and Perquisites			
Accrued Obligations	$ 33,291(3)	$ 33,291(3)	$ 33,291(3)
Benefits Continuation	$ —	$ 3,537(4)	$ 3,537(4)
Total Payments Upon Termination	$ 33,291	$ 164,328	$ 440,256

(1) Amount represents six months of his base salary then in effect.

(2) Amount represents the in-the-money value of unvested NewLink stock options as of June 30, 2011, using the value of the Company's common stock on December 31, 2010 based on the value of our common stock used for purposes of calculating compensation expense under ASC 718. The number of shares underlying such stock options and the exercise price thereof are reflected in the columns entitled "Number of Shares Underlying Unexercised Options—Unexercisable" and "Option Exercise Price," respectively, in the "Outstanding Equity Awards at June 30, 2011" table set forth on page 144 of this prospectus.

(3) Amount represents (i) a $22,000 contribution under the Company's 401(k) plan and (ii) $11,291 in accrued vacation.

(4) Amount represents six months of COBRA premiums.

Option Acceleration Under Equity Incentive Plans

Under our 2009 Equity Incentive Plan, the vesting of stock options granted to our employees and officers may be accelerated in connection with specified corporate transactions and change in control transactions.

Under the terms of the employment agreements with the named executive officers, if the Company (or any surviving or acquiring corporation) terminates a named executive officer's employment without just cause or a named executive officer resigns with good reason within one month prior to or 13 months following the effective date of a change in control of the Company, the Company will vest 100% of the shares subject to such named executive officer's options.

In addition, in the event of a change in control of the Company, the Company will vest 100% of the shares subject to each Director's options.

Other than as set forth above, none of our other option grants provide for acceleration of vesting of any options in connection with such a transaction, unless the acquirer does not assume outstanding option grants.

Confidential Information and Inventions Agreement

Each of our named executive officers has entered into a form agreement with respect to confidential information and inventions. Among other things, this agreement obligates each named executive officer to refrain from disclosing any of our confidential information received during the course of employment and, with some exceptions, to assign to us any inventions conceived or developed during the course of employment.

Employee Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate qualified service providers, and encourages them to devote their best efforts to our business and financial success. The material terms of our equity incentive plans are described below.

2000 Equity Incentive Plan

On April 10, 2000, the stockholders approved the Company's 2000 Equity Incentive Plan, or the 2000 Plan. As of July 15, 2009, no additional stock awards have been granted under the 2000 Plan and the 2000 Plan terminated according to its terms on March 2, 2010. As of June 30, 2011, options to purchase 1,164,072 shares of common stock at a weighted average exercise price per share of $0.90 were outstanding under the 2000 Plan.

2009 Equity Incentive Plan

On July 16, 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or the 2009 Plan, as the successor to and continuation of the 2000 Plan. The options still outstanding under the 2000 Plan will continue to be governed by their existing terms, but any shares subject to outstanding options granted under the 2000 Plan that expire or terminate for any reason prior to exercise or settlement, or are forfeited because of the failure to meet a contingency or condition required to vest such shares, will become available for issuance pursuant to awards granted under the 2009 Plan. In anticipation of our initial public offering, the 2009 Plan was amended by our Board of Directors on October 29, 2010.

Available Awards. The 2009 Plan provides for the discretionary grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards to our employees, directors and consultants. Incentive stock options may be granted only to employees of the Company or our affiliates.

Administration. Our Board of Directors has delegated its authority to administer the 2009 Plan to our Compensation Committee. Subject to the terms of the 2009 Plan, our Board of Directors or an authorized committee, referred to as the "plan administrator," determines: grant recipients, when and how each award will be granted, what type or combination of types of award will be granted, the provisions of each award granted (including the time or times when a person will be permitted to receive cash or

common stock pursuant to a stock award), the number of shares of common stock with respect to which a stock award will be granted, and the fair market value applicable to a stock award.

The plan administrator also has the authority, under appropriate circumstances, to engage in any action that is treated as a repricing under United States generally accepted accounting principles, to reduce the exercise price of any outstanding option or the strike price of any outstanding stock appreciation right, and to cancel any outstanding option or stock appreciation right and to grant in exchange one or more of the following: (i) new options or stock appreciation rights covering the same or a different number of shares of common stock; (ii) new stock awards; (iii) cash, and/or (iv) other valuable consideration.

Amendment and Termination. The plan administrator has the authority to amend the 2009 Plan, provided that certain changes require the approval of our stockholders. The 2009 Plan is scheduled to terminate on May 12, 2019, unless terminated earlier by the plan administrator.

Share Reserve. Subject to the provisions of the 2009 Plan relating to adjustments upon changes in stock, the aggregate number of shares of common stock that are available for issuance pursuant to stock awards (including incentive stock options) under the 2009 Plan is 8,385,000 shares. This amount will be increased pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. However, our Board of Directors will have the authority to designate a lesser number of shares by which the share reserve will be increased. As of June 30, 2011, options to purchase 5,371,559 shares of common stock at a weighted average exercise price per share of $1.51 were outstanding under the 2009 Plan. As of June 30, 2011, 1,514,322 shares of common stock remained available for future issuance. The shares remaining for future issuance as of June 30, 2011 will be reduced by an additional 854,000 shares of common stock issuable upon the exercise of options that will be granted effective concurrently with the pricing of this offering or as of December 31, 2011, if later.

If a stock award (a) granted under the 2009 Plan expires or otherwise terminates without all of the shares covered by such stock award having been issued or (b) granted under the 2009 Plan is settled in cash (i.e., the holder of the stock award receives cash rather than stock), such expiration, termination or settlement will not reduce or otherwise offset the number of shares of the common stock that may be issued pursuant to the 2009 Plan. In addition, if any shares of common stock issued pursuant to a stock award granted under the 2009 Plan are forfeited back to or repurchased by the Company because of the failure to vest, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the 2009 Plan. In addition, if any shares subject to a stock award are not delivered to a participant because the shares are reacquired by the Company to satisfy withholding obligations upon the exercise of an option, or as consideration for the exercise of an option, the number of shares subject to the stock award that are not delivered to the participant will also be available for subsequent issuance under the 2009 Plan. Subject to the provisions of the 2009 Plan relating to capitalization adjustments, the aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options will be 8,385,000 shares of common stock.

The stock issuable under the 2009 Plan may be shares of authorized but unissued or reacquired common stock, including shares repurchased by the Company on the open market.

Stock Options. Incentive and nonstatutory stock options are granted pursuant to incentive and nonstatutory stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2009 Plan, provided that the exercise price of an incentive stock option and nonstatutory stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2009 Plan vest at the rate specified by the plan administrator.

Generally, the plan administrator determines the term of stock options granted under the 2009 Plan, up to a maximum of 10 years, except in the case of specified incentive stock options, as described below.

Unless the terms of an optionee's stock option agreement provide otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases for any reason other than a termination for cause or a termination because of disability or death, the optionee may exercise the vested portion of any options for a period of three months following the cessation of service. If an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death (or an optionee dies within a specified period following cessation of service), the optionee or a beneficiary may exercise the vested portion of any options for a period of 12 months or 18 months, respectively. In the event of a termination of an optionee's services for cause, the unexercised portion of any outstanding stock option held by the optionee will be forfeited and may not be exercised. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include cash or check, a broker-assisted cashless exercise, the tender of common stock previously owned by the optionee, a net exercise of the option, and other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionee may designate a beneficiary, however, who may exercise the option following the optionee's death.

Tax Limitations on Incentive Stock Options. Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our equity incentive plans may not exceed $100,000. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and the term of the incentive stock option does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock is stock that is subject to certain restrictions, such as vesting or a holding period. The plan administrator may award restricted stock in consideration for past or future services without the payment of a purchase price, or in consideration for a cash payment or other legal consideration. Even while the restricted stock award is unvested, the award holder will have the same general rights as a stockholder with respect to those shares, including the right to vote those shares in any matter put to our stockholders for a vote.

Restricted Stock Unit Awards. A restricted stock unit award represents the right to receive consideration in the future based on the value of our common stock when the shares of common stock subject to the award have vested or are subsequently deliverable. Restricted stock unit awards may be settled by the delivery of shares of our common stock, their cash equivalent, a combination thereof, or any other form of consideration determined by the plan administrator and detailed in the award recipient's restricted stock unit award agreement. Unlike restricted stock, a holder of a restricted stock unit award does not have any rights as a stockholder until shares subject to the award are actually issued. Specifically, award holders do not have rights to vote the shares subject to their awards and will not have rights to receive dividends with respect to the shares subject to their awards, unless and until those shares are actually issued.

Performance Stock Awards. The 2009 Plan permits the grant of performance stock awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To assure that the compensation attributable to one or more performance stock awards will so qualify, our Compensation Committee can structure one or more such awards so that stock will be issued

or paid pursuant to such award only upon the achievement of certain pre-established performance goals during a designated performance period. The maximum benefit to be received by a participant in any calendar year attributable to performance stock awards may not exceed 500,000 shares of our common stock.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award and all other terms and conditions of such awards.

Adjustment Provisions. Transactions not involving our receipt of consideration, such as certain mergers, consolidations, reorganizations, stock dividends, or stock splits, may change the type, class and number of shares of our common stock subject to the 2009 Plan and outstanding awards. In that event, the 2009 Plan will be appropriately adjusted as to the type, class and the maximum number of shares of our common stock subject to the 2009 Plan, and outstanding awards will be adjusted as to the type, class, number of shares and price per share of common stock subject to such awards.

Corporate Transactions; Changes in Control. Unless otherwise determined by the Board of Directors at the time of grant, in the event of (i) a sale or other disposition of all or substantially all of the consolidated assets of our company and our subsidiaries, (ii) a sale or disposition of at least 90% of our outstanding securities, (iii) a merger consolidation or similar transaction after which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction after which we are the surviving corporation but our shares of common stock immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, any unvested portion of a stock award granted under the 2009 Plan held by those in continuous service as of the effective time of the corporate transaction will become fully vested, unless the surviving or acquiring corporation assumes or continues such outstanding stock award or substitutes a similar stock award for such outstanding stock award.

If a change in control occurs under the 2009 Plan, an individual stock award may provide for accelerated vesting upon the change in control. A change in control includes a transaction or series of related transactions, in each case, where persons who were not our stockholders immediately prior to acquiring our capital stock as part of such transaction become the owners of our capital stock that represents more than 50% of the combined voting power of our outstanding capital stock.

2010 Employee Stock Purchase Plan

On October 29, 2010, our Board of Directors adopted our 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, and our stockholders approved the 2010 Purchase Plan on January 7, 2011. The 2010 Purchase Plan will become effective upon the closing of the initial public offering.

Share Reserve. Subject to the provisions of the 2010 Purchase Plan relating to capitalization adjustments, the shares of common stock that may be sold pursuant to purchase rights shall not exceed in the aggregate 450,000 shares of common stock. If any purchase right granted under the 2010 Purchase Plan will for any reason terminate without having been exercised, the shares of common stock not purchased under such purchase right will again become available for issuance under the 2010 Purchase Plan. The 2010 Purchase Plan is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Administration. Our Board of Directors has delegated its authority to administer the 2010 Purchase Plan to our Compensation Committee. Subject to the terms of the 2010 Purchase Plan, our Board of Directors or an authorized Committee, referred to as the "plan administrator," determines the provisions of each offering of rights to purchase our common stock and whether employees of any of our parent or subsidiary companies will be eligible to participate in the 2010 Purchase Plan. The 2010 Purchase Plan will be implemented through a series of offerings of such duration as determined by the plan administrator to

eligible employees, provided that in no event may an offering exceed 27 months. Each offering will consist of one or more purchase periods as determined by the plan administrator prior to the commencement of that offering. The plan administrator has the authority to alter the duration of subsequent offerings or change the number of purchase dates within each such offering. The provisions of separate offerings need not be identical. When an eligible employee elects to join an offering, he or she will be granted a purchase right to acquire shares of common stock on each purchase date within the offering. On the purchase date, all payroll deductions collected from the participant are automatically applied to the purchase of common stock, subject to certain limitations. The plan administrator has not yet established the terms of any offering.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of any of our parent or subsidiary companies designated by the plan administrator may contribute, normally through payroll deductions, up to 15% of their eligible cash compensation (or such lesser amount set by the plan administrator for a specific offering) for the purchase of common stock under the 2010 Purchase Plan. Amounts deducted and accumulated for a participant are used to purchase shares of our common stock on the purchase dates established by the plan administrator. All payroll deductions made for a participant are credited to his or her account under the 2010 Purchase Plan and deposited with our general funds. A participant may make additional payments into such account only as specifically provided for in the offering and only if the participant has not exceeded certain limitations under the 2010 Purchase Plan or under the terms of such offering. The 2010 Purchase Plan permits common stock to be purchased at a price per share no less than the lower of (i) 85% of the fair market value of a share of our common stock on the offering date, or (ii) 85% of the fair market value of a share of our common stock on the applicable purchase date.

Purchase of Stock. An eligible employee must sign and return an agreement in order to participate in the 2010 Purchase Plan. In connection with offerings made under the 2010 Purchase Plan, the plan administrator may specify a maximum number of shares of common stock a participant may purchase and the maximum aggregate number of shares of common stock that may be purchased by all participants in such offering. In addition, in connection with each offering that contains more than one purchase date, the plan administrator may specify a maximum aggregate number of shares of common stock that may be purchased by all participants on any purchase date under the offering. If the aggregate number of shares to be purchased upon exercise of outstanding purchase rights in the offering would exceed the maximum aggregate number of shares of common stock available, the plan administrator will make a pro rata allocation of available shares in a uniform and equitable manner. Unless the employee's participation is discontinued, his or her right to purchase shares is exercised automatically at the next purchase date at the applicable price.

Withdrawal. During an offering, a participant may cease making contributions and withdraw from the offering by delivering a notice of withdrawal and terminating his or her payroll deductions in such form as we may require. Such withdrawal may occur at any time prior to the end of an offering except as otherwise provided by the plan administrator. Upon such withdrawal, we will refund accumulated payroll deductions without interest to the employee, and such employee's right to participate in that offering will terminate. However, an employee's withdrawal from an offering does not generally affect such employee's eligibility to participate in subsequent offerings under the 2010 Purchase Plan.

Reset Feature. The plan administrator has the authority to provide that if the fair market value of the shares of our common stock on the first day of a new purchase period within a particular offering is less than the fair market value of the shares of common stock on the start date of that offering, then the participants in that offering will automatically be transferred and enrolled in a new offering which will begin on the first day of that purchase period and the participant's purchase rights in the original offering will terminate.

Limitations. The plan administrator may limit participation in the 2010 Purchase Plan to those persons who are customarily employed more than 20 hours per week and five months per calendar year by us (or by any of our parent or subsidiary companies designated by the plan administrator) on the first day of an offering. The plan administrator may also provide that a person must have been employed for such continuous period preceding the first day of the offering as the plan administrator may require, but in no event may the required period of continuous employment be greater than two years. In addition, the plan administrator may provide in any offering that certain of our employees who are "highly compensated" as defined in the Code are not eligible to participate in the 2010 Purchase Plan. The plan administrator may also provide that each person who, during the course of an offering, first becomes an eligible employee will, on a date or dates specified in the offering, receive a purchase right under that offering at a price equal to the market price of our common stock at that time, which purchase right will be deemed to be a part of that offering, and such purchase right will generally have the same characteristics as any purchase rights originally granted under that offering. No employee is eligible to participate in the 2010 Purchase Plan if, immediately after the grant of purchase rights, the employee would own, directly or indirectly, stock possessing 5% or more of the total combined voting power or value of all classes of our stock or of any of our parent or subsidiary companies (including any stock which such employee may purchase under all outstanding purchase rights and stock options). In addition, no employee may purchase more than $25,000 worth of our common stock (valued at the time each purchase right is granted) for each calendar year during which those purchase rights are outstanding.

Termination of Employment. Purchase rights granted pursuant to any offering under the 2010 Purchase Plan terminate upon cessation of employment for any reason, and we will refund all accumulated payroll deductions to the terminated employee without interest.

Restrictions on Transfer. A participant may not transfer rights granted under the 2010 Purchase Plan other than by will, the laws of descent and distribution, or by a beneficiary designation as provided in the 2010 Purchase Plan. During a participant's lifetime, purchase rights will be exercisable only by such participant.

Changes to Capital Structure. In the event that there is any change to the outstanding common stock (whether by reason of merger, consolidation, reorganization, recapitalization, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or other transaction not involving the receipt of consideration by the Company), appropriate adjustments will be made to (a) the class and maximum number of securities subject to the 2010 Purchase Plan, (b) the class and maximum number of securities by which the share reserve is to increase automatically each year, (c) the class and number of securities subject to outstanding purchase rights, and (d) the class and number of securities imposed by purchase limits under each ongoing offering.

Corporate Transactions. In the event of certain significant corporate transactions, any surviving or acquiring corporation may assume, continue or substitute similar purchase rights for those outstanding under the 2010 Purchase Plan. If the surviving or acquiring corporation does not assume or continue such rights or substitute similar rights, then the participants' accumulated payroll deductions will be used to purchase shares of common stock within ten business days prior to the corporate transaction under any ongoing offerings, and such purchase rights will terminate immediately thereafter.

Termination and Amendment. The plan administrator may amend, suspend or terminate the 2010 Purchase Plan at any time. Any amendment of the 2010 Purchase Plan must be approved by our shareholders to the extent shareholder approval is necessary for the 2010 Purchase Plan to satisfy Sections 423 of the Code or other applicable laws and regulations. Purchase rights granted before amendment, suspension or termination of the 2010 Purchase Plan generally may not be altered or impaired by any amendment, suspension or termination of the 2010 Purchase Plan without consent of the

employee to whom such purchase rights were granted. No purchase rights may be granted under the 2010 Purchase Plan while the 2010 Purchase Plan is suspended or after it is terminated.

2010 Non-Employee Directors' Stock Award Plan

Our Board of Directors adopted the Non-Employee Directors' Stock Award Plan, or Directors' Plan, on October 29, 2010 and our stockholders approved the Directors' Plan on January 7, 2011. The Directors' Plan will become effective immediately upon the execution and delivery of the underwriting agreement for this offering. The Directors' Plan will terminate at the discretion of our Board of Directors. The purpose of the Directors' Plan is to retain the services of new non-employee directors and provide incentives for such persons to exert maximum efforts towards our success by giving them an opportunity to benefit from increases in value of our common stock. The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of our common stock to our non-employee directors. The Directors' Plan also provides for the discretionary grant of stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards.

Share Reserve. An aggregate of 500,000 shares of our common stock are reserved for issuance under the Directors' Plan. Shares of our common stock subject to stock awards that have expired or otherwise terminated under the Directors' Plan without having been exercised in full will again become available for grant under the Directors' Plan. Shares of our common stock issued under the Directors' Plan may be previously unissued shares or reacquired shares bought on the market or otherwise. If the exercise of any stock option granted under the Directors' Plan is satisfied by tendering shares of our common stock held by the participant, then the number of shares tendered will again become available for the grant of awards under the Directors' Plan. In addition, any shares reacquired to satisfy income or employment withholding taxes will again become available for the grant of awards under the Directors' Plan.

Administration. Our Board of Directors has delegated its authority to administer the Directors' Plan to our Compensation Committee. The Compensation Committee must consist of two or more "non-employee directors" pursuant to the Rule 16b-3 of the Securities Exchange Act of 1934, as amended.

Stock Options. Stock options will be granted pursuant to stock option agreements. The exercise price of the options granted under the Directors' Plan will be equal to 100% of the fair market value of our common stock on the date of grant.

In general, the term of stock options granted under the Directors' Plan may not exceed ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any affiliate of ours, ceases due to death or disability, the optionholder or his or her beneficiary may then exercise any vested options for a period of 12 months in the event of disability, or 18 months in the event of death. If an optionholder's service with us or any affiliate ceases for any other reason, the optionholder may exercise the vested options for up to three months following cessation of service.

Acceptable consideration for the purchase of our common stock issued under the Directors' Plan may include cash, a net exercise, common stock previously owned by the optionholder or a program developed under Regulation T as promulgated by the Federal Reserve Board.

Generally, an optionholder may not transfer a stock option other than by will or the laws of descent and distribution. However, an optionholder may transfer an option under certain circumstances with our written consent if a Form S-8 registration statement is available for the exercise of the option and the subsequent resale of the shares. In addition, an optionholder may designate a beneficiary who may exercise the option following the optionholder's death.

Non-discretionary Grants

- *Initial Grant.* Any person who becomes a non-employee director for the first time after the completion of this offering will automatically receive an initial grant of an option to purchase 25,000 shares of our common stock upon his or her election or appointment, subject to adjustment by our Board of Directors from time to time. 33% of the shares subject to the initial grants will vest on the first anniversary of the date of such person's election or appointment to the Board of Directors and the remainder will vest monthly over two additional years. These initial grants may also be issued in the form of stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards, or other stock awards if so determined by our Board of Directors.
- *Annual Grant.* In addition, on the date of the annual meeting of our stockholders, commencing with our first annual meeting after the completion of this offering, any person who is a non-employee director on such date automatically will be granted an option to purchase 15,000 shares of our common stock, plus an additional 7,500 shares of our common stock for service as chair of the Audit, Compensation or Nominating and Corporate Governance Committee, or as Lead Independent Director as of such date, plus 5,000 shares of our common stock for service as a member of the Audit, Compensation or Nominating and Corporate Governance Committee as of such date, subject to adjustment by our Board of Directors from time to time. Fifty percent of the shares subject to the annual grants will vest on the first anniversary of the date of grant and the remainder will vest monthly over one additional year, subject to continued employment. These annual grants may also be issued in the form of SARs, restricted stock awards, restricted stock unit awards, or other stock awards if so determined by our Board of Directors.

Discretionary Grants

In addition to the non-discretionary grants noted above, our Board of Directors may grant stock awards to one or more non-employee directors in such numbers and subject to such other provisions as it shall determine. These awards may be in the form of stock options, SARs, restricted stock awards, restricted stock units, or other stock awards and will vest pursuant to vesting schedules to be determined by our Board of Directors in its sole discretion.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure not involving the receipt of consideration by us, such as a stock split or stock dividend, the number of shares reserved under the Directors' Plan, the maximum number of shares by which the share reserve may increase automatically each year, the number of shares subject to the initial and annual grants and the number of shares and exercise price of all outstanding stock options will be appropriately adjusted.

Change in Control Transactions. In the event of a change in control transaction, the vesting of options held by non-employee directors whose service is terminated may be accelerated in full according to the provisions of the award agreement. A change in control is the occurrence of one or more of the following events:

- a transaction in which one person or a group acquires stock that, combined with stock previously owned, controls more than 50% of our value or voting power;
- a merger, consolidation or similar transaction involving us (directly or indirectly) in which the our stockholders immediately before the transaction do not own more than 50% of the outstanding securities following such transaction;
- our complete liquidation or dissolution;
- a sale, lease, license or other disposition of substantially all of our assets; or
- a majority of the Board of Directors is replaced by persons whose appointment or election is not endorsed by a majority of the Board of Directors.

Plan Amendments. Our Board of Directors will have the authority to amend, suspend or terminate the Directors' Plan. However, no amendment or termination of the directors' plan will adversely affect any rights under awards already granted to a participant unless agreed to by the affected participant. We will obtain stockholder approval of any amendment to the Directors' Plan that is required by applicable law.

Indebtedness of Management and Related Agreements

In 2008, in connection with his commencement of employment and relocation to Ames, Iowa, we entered into a loan agreement with Mr. Gordon Link, our Chief Financial Officer. Pursuant to the terms of this agreement, we loaned Mr. Link $500,000 for the purchase of a principal residence. This note was secured by Mr. Link's residence and had an interest rate of 2.42% per year. In May 2010, Mr. Link repaid the loan in full and we forgave accrued interest of $10,052.

In 2008, we entered into a loan agreement with Dr. Charles Link, our Chief Executive Officer. Pursuant to this agreement, we loaned Dr. Link $225,000 for personal purposes. This loan had an interest rate of 6% per year. In January 2009, we granted Dr. Link a bonus of $78,149, which was applied to the principal due on the loan. In April 2009, Dr. Link repaid the remaining principal and accrued interest on the loan.

In 2009, we entered into another loan agreement with Dr. Link. Pursuant to this agreement, we loaned Dr. Link $350,000 for personal purposes. This loan had an interest rate of 6% per year. In July 2010, we forgave the loan and accrued interest of $25,170 and granted Dr. Link a $180,226 bonus to pay the taxes incurred as a result of such extinguishment. To offset the forgiveness and the bonus payment, the exercise price of options to purchase 555,396 shares of common stock held by Dr. Link from was increased from $1.00 per share to $2.00 per share and Dr. Link agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

In 2000, we loaned Dr. Vahanian, our President and Chief Medical Officer $31,500. This loan had an interest rate of 6.71% per year. In July 2010, we forgave the remaining balance of $25,000 and all accrued interest and granted Dr. Vahanian a $12,010 bonus to pay the taxes incurred as a result of such extinguishment. To offset the forgiveness and the bonus payment, the exercise price of options to purchase 37,010 shares of common stock held by Dr. Vahanian from was increased from $1.00 per share to $2.00 per share and Dr. Vahanian agreed to exercise the higher priced options prior to exercising any lower priced options to purchase our common stock.

In 2008, we entered into another loan agreement with Dr. Vahanian. Pursuant to this agreement, we loaned Dr. Vahanian $125,000 for personal purposes. This loan had an interest rate of 6% per annum. In January 2009, we granted Dr. Vahanian a bonus of $55,037, which was applied to the principal due on the loan. In April 2009, Dr. Vahanian repaid the remaining principal and all accrued interest on the loan.

In 2006, BPS entered into a loan agreement with Dr. Charles Link. Pursuant to this agreement, BPS loaned Dr. Link $75,000 to facilitate the exercise of stock options. The loan had an interest rate of 5.01% per annum. In March 2010 and May 2010, BPS forgave a total of $30,000 of the principal amount of the loan plus $13,517 of interest accrued on the loan. In March 2010, BPS paid Dr. Link a cash bonus of $15,000 to cover related tax liability. In October 2010, BPS paid Dr. Link a bonus of $50,000 gross, of which $33,775 was net and was applied to the principal due on the loan. In November 2010, Dr. Link repaid the remaining principal and all accrued interest on the loan.

In 2006, BPS entered into a loan agreement with Dr. Vahanian. Pursuant to this agreement, BPS loaned Dr. Vahanian $20,000 to facilitate the exercise of stock options. The loan had an interest rate of 5.01%. In March 2010 and May 2010, BPS forgave a total of $8,000 of the principal amount of the loan plus $3,604 of interest accrued on the loan and paid Dr. Vahanian a cash bonus, a portion of which was used to cover the related tax liability. In October 2010, Dr. Vahanian repaid the remaining principal and all accrued interest on the loan.

Limitation of Liability and Indemnification

Our amended and restated bylaws to be in effect upon the closing of this offering require us to indemnify our directors to the fullest extent not prohibited by law and permit us to indemnify our officers, employees and other agents as set forth under Delaware law. We will indemnify any such person in connection with a proceeding initiated by such person only if such indemnification is expressly required by law, the proceeding was authorized by our Board of Directors, the indemnification is provided by us, in our sole discretion, pursuant to the Delaware General Corporation Law or other applicable law or is otherwise expressly required by our amended and restated bylaws. Section 145 of the Delaware General Corporation Law permits indemnification of officers, directors and other agents under specified circumstances and subject to specified limitations. Delaware law also permits a corporation to not hold its directors personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for:

- breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity. We have obtained directors' and officers' liability insurance to cover certain liabilities described above.

We have entered into indemnity agreements with each of our directors that require us to indemnify such persons against any and all expenses, including attorneys' fees, witness fees, judgments, fines, settlements and other amounts incurred, including expenses of a derivative action, in connection with any action, suit or proceeding or alternative dispute resolution mechanism, inquiry hearing or investigation, whether threatened, pending or completed, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of our company, provided that such person's conduct did not constitute a breach of his or her duty of loyalty to us or our stockholders, and was not an act or omission not in good faith or which involved intentional misconduct or a knowing violation of laws. The indemnity agreements also set forth procedures that will apply in the event of a claim for indemnification thereunder. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors of our company.

At present, there is no pending litigation or proceeding involving a director or officer of our company for which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted by directors, executive officers or persons controlling us, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Non-Employee Director Compensation

The following table shows certain information with respect to the compensation of all non-employee directors of the Company for the fiscal year ended December 31, 2010.

2010 Director Compensation

Name	Option Awards($)(1)	Fair Value(2)
Thomas A. Raffin, M.D.	$ 330,725(3)	$ 234,150
Sarah Alexander M.D., F.A.C.P.	$ 153,800(4)	$ 117,769
David J. Lundquist	$ 187,625(5)	$ 147,489
Joseph Saluri	$ 218,050(6)	$ 153,598
Ernest J. Talarico, III	$ 289,100(7)	$ 232,673

(1) Unless otherwise indicated, these options have a 10-year term and vest over a two-year period, with 50% of the options vesting on the first anniversary of the vesting commencement date and the remaining 50% of the options vesting in equal monthly installments thereafter over the next year, subject to the recipient's continued service with the Company through such vesting dates.

(2) Fair value was determined using a Black-Scholes model which allows the use of a range of assumptions related to volatility, risk-free interest rate, and employee exercise behavior.

(3) Represents (i) 55,000 options exercisable at $1.46 per share with a vesting commencement date of March 3, 2010, (ii) 15,000 options exercisable at $4.77 per share with a vesting commencement date of December 9, 2010 and (iii) 37,500 options exercisable at $4.77 per share with a vesting commencement date of January 1, 2011.

(4) Represents (i) 40,000 options exercisable at $1.46 per share with a vesting commencement date of March 3, 2010 and (ii) 20,000 options exercisable at $4.77 per share with a vesting commencement date of January 1, 2011.

(5) Represents (i) 55,000 options exercisable at $1.46 per share with a vesting commencement date of March 3, 2010 and (ii) 22,500 options exercisable at $4.77 per share, with a vesting commencement date of January 1, 2011.

(6) Represents (i) 35,000 options exercisable at $1.46 per share with a vesting commencement date of March 3, 2010, (ii) 30,000 options exercisable at $4.77 per share with a vesting commencement date of January 1, 2011 and (iii) 5,000 options at $4.77 per share with a vesting commencement date of December 9, 2010.

(7) Represents (i) 50,000 options exercisable at $1.46 per share with a vesting commencement date of March 3, 2010, (ii) 50,000 options exercisable at $1.46 per share that are fully vested, (iii) 5,000 options exercisable at $4.77 per share with a vesting commencement date of December 9, 2010 and (iv) 25,000 options exercisable at $4.77 per share with a vesting commencement date of January 1, 2011.

In December 2009, the Board of Directors adopted our non-employee director compensation policy, pursuant to which non-employee directors are compensated for their services on our Board. This policy was revised by our Board of Directors in October 2010. The Non-Employee Directors Stock Award Plan will supersede the policy described above effective upon closing of the initial public offering. Under the current policy, for service on the Board of Directors each non-employee director receives an initial option grant of 25,000 shares of the company's common stock, of which 33% vests on the first anniversary of the director's election or appointment and the remainder vests on a monthly basis over the subsequent two years. Additionally, each non-employee director receives, during the term of his or her service on the Board of Directors, an annual option grant of 15,000 shares, plus 7,500 shares for service as chair of the

Audit, Compensation or Nominating and Corporate Governance Committee, or as Lead Independent Director. In addition, a director receives 5,000 shares for service as a member of (but not as chair of) the Audit, Compensation and/or Nominating and Corporate Governance Committee. For example, a director serving as chair of the Audit Committee and as a member of the Compensation Committee and the Nominating and Corporate Governance Committee would receive, immediately following the date of our annual meeting of stockholders, an annual grant of 32,500 shares (i.e., 15,000 + 7,500 + 5,000 + 5,000). The annual option grants vest as to 50% of the shares one year after the date of grant and the remainder over the succeeding twelve months.

Historically, we have not provided cash compensation to any directors for serving on our Board of Directors or committees of our Board of Directors. Commencing with the closing of the initial public offering, the Company will pay annual cash retainers to directors (other than executive officers) as follows:

All Directors (other than executive officers)	$ 50,000
Lead Independent Director	$ 15,000
Audit Committee Chair	$ 20,000
Other Audit Committee Members	$ 13,500
Compensation Committee Chair	$ 14,000
Other Compensation Committee Members	$ 7,500
Nominating and Corporate Governance Committee Chair	$ 7,500
Other Nominating and Corporate Governance Committee Members	$ 5,000

Payments for service as lead director, committee chair or committee member are in addition to payment for service as a director. Payments will be made quarterly beginning on the first day of the quarter following closing of the initial public offering.

We have reimbursed and will continue to reimburse our non-employee directors for their reasonable expenses incurred in attending meetings of our Board of Directors and committees of our Board of Directors.

No cash compensation was paid to directors in 2010 or in the six-month period ending June 30, 2011.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our inception to which we have been a party, in which the amount involved in the transaction exceeds $120,000, and in which any of our directors, executive officers or to our knowledge, beneficial owners of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under the "Executive and Director Compensation" section of this prospectus. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions.

Preferred Stock Financings

On August 29, 2000, we entered into a Series A Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 420,000 shares of Series A preferred stock on August 29, 2000 at a purchase price of $2.50 per share, for aggregate consideration of $1.1 million.

On September 26, 2001, we entered into a Series AA Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 1,224,967 shares of Series AA preferred stock at a purchase price of $1.80 per share, for aggregate consideration of $2.2 million.

On January 21, 2002, we entered into a Series AAA Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 377,410 shares of Series AAA preferred stock at a purchase price of $2.25 per share, for aggregate consideration of $850,000.

Between October 7, 2002 and December 12, 2003, we entered into Series B Preferred Stock Purchase Agreements pursuant to which we issued and sold to investors an aggregate of 2,191,193 shares of Series B preferred stock at a purchase price of $2.50 per share, for aggregate consideration of $5.5 million.

On February 11, 2005, we entered into a Series BB Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 1,906,866 shares of Series BB preferred stock at a purchase price of $4.25 per share, for aggregate consideration of $8,104,181.

Between February 8, 2008 and December 17, 2009, we entered into Series C Preferred Stock Purchase Agreements pursuant to which we issued and sold to investors an aggregate of 6,000,000 shares of Series C preferred stock at a purchase price of $5.00 per share, for aggregate consideration of $30.0 million.

On July 17, 2009, we entered into a Series D Preferred Stock Purchase Agreement pursuant to which we issued and sold to one investor 1,500,000 shares of Series D preferred stock at a purchase price of $5.00 per share, for aggregate consideration of $7.5 million.

Between December 1, 2010 and June 30, 2011, we issued and sold to investors an aggregate of 684,624 shares of our Series E preferred stock at a purchase price of $31.25 per share, for aggregate consideration of $21.4 million.

The participants in these preferred stock financings included the following directors, officers and holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in these financings. Upon completion of this offering, each share of Series A preferred stock will convert into 1.389 shares of our Common Stock; each share of Series AA, AAA, B, C and D preferred stock will convert into one share of our Common Stock; and each share of Series E preferred stock will convert into the number of shares of Common Stock obtained by dividing $31.25 by the Series E conversion price. The Series E conversion price is currently $6.25. If the Company closes this offering on or before December 31, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of the Company's Common Stock are sold to the public in this offering and (B) 0.85 (as adjusted appropriately to reflect any

adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this offering).

Name	Shares of Series A Convertible Preferred Stock	Shares of Series AA Convertible Preferred Stock	Shares of Series AAA Convertible Preferred Stock	Shares of Series B Convertible Preferred Stock	Shares of Series C Convertible Preferred Stock	Shares of Series D Convertible Preferred Stock	Shares of Series E Convertible Preferred Stock
5% or Greater Stockholders							
Stine Seed Farm Inc.(1)	—	—	—	1,760,000	1,000,000	1,500,000	320,000
Executive Officers and Directors							
Sarah Alexander, M.D. F.A.C.P.	—	—	11,112	—	1,000	—	—
David J. Lundquist	—	27,780(2)	—	19,999(2)	20,000(2)	—	—
Nicholas N. Vahanian, M.D.	40,000	—	—	—	—	—	—
Joseph Saluri	—	—	—	—	15,000	—	—
Ernest J. Talarico, III	—	—	—	—	5,000(3)	—	—

(1) On October 8, 2010, Midwest Oilseeds transferred all of its shares of the Company's stock to Stine Seed Farm Inc.

(2) These shares belong to the David Lundquist Revocable Trust.

(3) These shares are held by NLG Series C, LLC.

Agreements With Our Stockholders

We have entered into an investor rights agreement with holders of our convertible preferred stock and warrants to purchase shares of our common stock. The investor rights agreement contains a right of first refusal provision that provides that we shall not make certain issuances of our securities unless we first offer such securities to certain holders of preferred stock in accordance with the terms of the investor rights agreement. The right of first refusal provision of the investor rights agreement does not apply to and will terminate upon the closing of this offering. The investor rights agreement also provides that holders of preferred stock and warrants to purchase common stock have the right to (a) demand that we file a registration statement, subject to certain limitations, and (b) request that their shares be covered by a registration statement that we are otherwise filing. See the "Description of Capital Stock—Registration Rights" section of this prospectus for a further discussion of these registration rights.

We have also entered into a right of first refusal and co-sale agreement with holders of convertible preferred stock and certain other stockholders. This agreement provides the holders of preferred stock a right of purchase and of co-sale in respect of sales of securities by certain holders of common stock. These rights of purchase and co-sale will terminate upon the closing of this offering.

We have also entered into a voting agreement with our equity holders that contains agreements with respect to the election of our Board of Directors and its composition. The voting agreement will terminate upon the closing of this offering.

Each of the transactions noted above were entered into prior to our adoption of a written related party transaction policy, which is described below.

BPS Preferred Stock Financings

Between December 30, 2005 and February 28, 2006, BPS entered into Series A Preferred Stock Purchase Agreements pursuant to which BPS issued and sold to investors an aggregate of 1,444,721 shares of its Series A preferred stock at a purchase price of $1.75 per share, for aggregate consideration of $2.5 million.

Between December 22, 2009 and September 7, 2010, BPS entered into Series B Preferred Stock Purchase Agreements pursuant to which BPS issued and sold to investors an aggregate of 555,930 shares of its Series B preferred stock at a purchase price of $1.75 per share, for aggregate consideration of $973,000.

Acquisition of BioProtection Systems Corporation

On January 7, 2011, we acquired all of the minority interest in our majority-owned subsidiary, BPS, by merging a newly-formed subsidiary of ours with BPS, with BPS as the surviving corporation. In connection with this transaction, we will issue up to an aggregate of 276,304 shares of our Series E preferred stock to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than the Company). 221,066 of the shares of our Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of our Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. The remaining 55,238 shares subject to the holdback were issued August 12, 2011. As a result of this transaction, BPS became a wholly-owned subsidiary of the Company and our note was converted into Series B preferred stock of BPS. All options to purchase shares of BPS stock became options to purchase a total of 106,347 shares of our common stock.

In this transaction, shares of our Series E preferred stock were issued to our officers and directors as follows:

Name	Shares of Series E Preferred Stock Issued at Closing of the Merger	Shares of Series E Preferred Stock Issued August 12, 2011
Charles J. Link, Jr., M.D.	41,568	10,392
Nicholas N. Vahanian, M.D.	11,085	2,771
Thomas A. Raffin, M.D.	1,386	346
Ernest J. Talarico, III	1,386	346

In addition, the following directors and officers of NewLink who are also directors or officers of BPS exchanged their BPS stock options for options to acquire NewLink common stock as follows:

Name	Options to Acquire BPS Series B Common Stock	Options to Acquire NewLink Common Stock
Charles J. Link, Jr., M.D.	20,000	5,385
Nicholas N. Vahanian, M.D.	20,000	5,385
Thomas A. Raffin, M.D.	50,000	13,462
Ernest J. Talarico, III	45,000	12,116

The acquisition of BPS was recommended by a special committee of our Board of Directors consisting of Dr. Alexander and Messrs. Lundquist and Saluri, none of whom served as directors of BPS. Dr. Alexander and Mr. Saluri did not own any shares or options in BPS. The David Lundquist Revocable Trust owned shares of Series A Preferred Stock in BPS.

Executive Compensation and Employment Arrangements

Please see the "Executive and Director Compensation" section of this prospectus for information on compensation arrangements with our executive officers, including option grants and agreements with executive officers.

Director Compensation

Please see the "Executive and Director Compensation—Non-Employee Director Compensation" section of this prospectus for information on compensation arrangements for our directors generally.

Other Transactions

We have made loans to certain of our executive officers. For a description of these loans, see the "Executive and Director Compensation—Indebtedness of Management and Related Agreements" section of this prospectus.

Policies and Procedures for Related Person Transactions

Our Board of Directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which we are a participant, the amount involved exceeds $120,000 and one of our executive officers, directors, director nominees or 5% stockholders (or their immediate family members), each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to the Audit Committee of our Board of Directors. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by the Audit Committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the Audit Committee will review, and, in its discretion, may ratify the related person transaction. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the Audit Committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unaffiliated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The Audit Committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent, with our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related person transaction disclosure rule, our Board of Directors has determined that the following transactions do not

create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity (whether or not the person is also a director of such entity), that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction or (c) the amount involved in the transaction equals less than the greater of $200,000 or 5% of the annual consolidated gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our charter or by-laws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the Compensation Committee in the manner specified in its charter.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of June 30, 2011 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage of shares beneficially owned before the offering shown in the table is based upon shares of common stock outstanding as of June 30, 2011, after giving effect to (i) the issuance of 276,304 shares of our Series E preferred stock in connection with our acquisition of the minority interest in BPS and (ii) the conversion of all of our convertible preferred stock into shares of common stock, which will occur automatically immediately prior to the closing of this offering. The information relating to numbers and percentages of shares beneficially owned after the offering gives effect to the issuance of shares of common stock in this offering, assuming the initial public offering price in this offering is $ per share, the midpoint of the range set forth on the cover page of this prospectus, and assuming that this offering is closed on , 2011.

The number of shares of common stock, as reflected above, that we assume will be issued upon conversion of our preferred stock is based on an assumed initial public offering price equal to $, which is the midpoint of the range listed on the cover page of this prospectus. If our initial public offering price is less than $5.00 per share, after deducting underwriting discounts and commissions, shares of the Series C and Series D preferred stock will be converted into more than one share of common stock, and if our initial public offering price is less than $4.25 per share, after deducting underwriting discounts and commissions, shares of the Series BB preferred stock will be converted into more than one share of common stock, in each case due to the application of antidilution adjustments with respect to the conversion prices of the preferred stock under our Restated Certificate of Incorporation. The number of shares of common stock that will be issued upon conversion of the Series E preferred Stock depends upon the initial public offering price, regardless of the specific offering price. A $1.00 increase in the assumed initial public offering price would decrease the aggregate number of shares of common stock issuable upon conversion of the Series C, D and E preferred stock from the amount set forth above by shares; a $1.00 decrease in the assumed initial public offering price would increase the aggregate number of shares of common stock issuable upon conversion of the Series BB, C, D and E preferred stock from the amount set forth above by shares.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before August 29, 2011, which is 60 days after June 30, 2011. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons listed in the table is c/o NewLink Genetics Corporation, 2503 South Loop Drive, Ames, Iowa 50010.

Name of Beneficial Owner	Shares Beneficially Owned Before Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
5% Stockholders:				
Stine Seed Farm, Inc**	6,235,000(1)	25.1%		
Named Executive Officers and Directors:				
Charles J. Link, Jr. M.D.	4,489,017(2)	17.0%		
Nicholas N. Vahanian, M.D.	1,539,387(3)	5.9%		
Thomas A. Raffin, M.D.	274,958(4)	1.1%		
Kenneth Lynn	188,596(5)	0.8%		
Ernest J. Talarico, III	252,570(6)	1.0%		
David Lundquist	195,912(7)	0.8%		
Gordon H. Link, Jr.	166,058(8)	0.7%		
W. Jay Ramsey M.D., Ph.D.	133,583(9)	0.5%		
Sarah Alexander, M.D., F.A.C.P.	75,445(10)	0.3%		
Joseph Saluri	31,527(11)	0.1%		
Paul R. Edick	0(12)	0%		
All current directors and executive officers as a group (11 persons)	7,347,053(13)	25.7%		

* Represents beneficial ownership of less than 1%.

** Address: 22555 Laredo Trail, Adel, Iowa 50003, Attn: Jerald L Reichling

(1) Includes 320,000 shares of NewLink Series E preferred stock. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

(2) Includes 1,659,677 shares Dr. Charles Link has the right to acquire through the exercise of stock options within 60 days of June 30, 2011. Includes 51,960 shares of NewLink Series E preferred stock issued in connection with our acquisition of BPS in exchange for 1,500,000 shares of BPS Series B common stock currently held by Dr. Link. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

(3) Includes 111,000 shares held by Christina Marie Vahanian, and 1,162,551 shares Dr. Vahanian has the right to acquire through the exercise of stock options within 60 days of June 30, 2011. Includes 13,856 shares of NewLink Series E preferred stock issued in connection with our acquisition of BPS in exchange for 400,000 shares of BPS Series B common stock currently held by Dr. Vahanian. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

(4) Includes 166,298 shares Dr. Raffin has the right to acquire through the exercise of stock options within 60 days of June 30, 2011. Includes 1,732 shares of NewLink Series E preferred stock issued in connection with our acquisition of BPS in exchange for 50,000 shares of BPS Series B common stock currently held by Dr. Raffin. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this

offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above. Excludes 7,500 shares of our common stock issuable upon exercise of stock options granted to Dr. Raffin by our Board of Directors on July 29, 2011, which will not become effective until the pricing of the Company's initial public offering.

(5) Includes 188,596 shares Mr. Lynn has the right to acquire through the exercise of stock options within 60 days of June 30, 2011.

(6) Includes 213,910 shares Mr. Talarico has the right to acquire through the exercise of stock options within 60 days of June 30, 2011. Includes 5,000 shares of NewLink Series C preferred stock held by NLG Series C, LLC. Includes 1,732 shares of NewLink Series E preferred stock issued in connection with our acquisition of BPS in exchange for 50,000 shares of BPS Series B common stock currently held by Mr. Talarico. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

(7) Includes 116,954 shares held by David Lundquist Revocable Trust, dated November 19, 2002, David J. Lundquist, Trustee, and 78,958 shares Mr. Lundquist has the right to acquire through the exercise of stock options within 60 days of June 30, 2011. Includes 5,257 shares of NewLink Series E preferred stock issued in connection with our acquisition of BPS in exchange for 58,000 shares of BPS Series A preferred stock currently held in the David Lundquist Revocable Trust. Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends on the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the numbers set forth above.

(8) Includes 166,058 shares Mr. Gordon Link has the right to acquire through the exercise of stock options within 60 days of June 30, 2011.

(9) Includes 83,583 shares Dr. Ramsey has the right to acquire through the exercise of stock options within 60 days of June 30, 2011.

(10) Includes 63,333 shares Dr. Alexander has the right to acquire through the exercise of stock options within 60 days of June 30, 2011.

(11) Includes 16,527 shares Mr. Saluri has the right to acquire through the exercise of stock options within 60 days of June 30, 2011.

(12) In connection with Mr. Edick's appointment to our Board of Directors on July 29, 2011, he was granted the right to acquire 25,000 shares of our common stock through the exercise of stock options that will not become effective until the pricing of the Company's initial public offering.

(13) Includes 3,799,491 shares issuable upon exercise of stock options by all executive officers and directors exercisable within 60 days of June 30, 2011. See notes (2) through (11) above.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws, each to be in effect upon the completion of this offering. We have filed copies of these documents with the Securities and Exchange Commission, or SEC, as exhibits to our registration statement of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering. Upon the closing of this offering and the filing of the amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.01 per share, and shares of preferred stock, par value $0.01 per share, all of which preferred stock will be undesignated.

As of June 30, 2011, we had issued and outstanding:

- 7,662,222 shares of our common stock held by 113 stockholders of record;
- 420,000 shares of our Series A preferred stock held by eight stockholders of record that are convertible into an aggregate of 583,333 shares of our common stock;
- 1,217,175 shares of our Series AA preferred stock held by 32 stockholders of record are convertible into shares of our common stock on a one-for-one basis;
- 377,410 shares of our Series AAA preferred stock held by 18 stockholders of record that are convertible into shares of our common stock on a one-for-one basis; and
- 2,191,193 shares of our Series B preferred stock held by 18 stockholders of record that are convertible into shares of our common stock on a one-for-one basis.
- 1,883,337 shares of our Series BB preferred stock held by 92 stockholders of record that are convertible into shares of our common stock on a one-for-one basis;
- 6,000,000 shares of our Series C preferred stock held by 152 stockholders of record that are convertible into shares of our common stock on a one-for-one basis; and
- 1,500,000 shares of our Series D preferred stock held by one stockholder of record that are convertible into shares of our common stock on a one-for-one basis.
- 680,998 shares of our Series E preferred stock held by 78 stockholders of record that are convertible into the number of shares of our common stock obtained by dividing $31.25 by the Series E conversion price. The Series E conversion price is currently $6.25. If we close this offering on or before December 31, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of common stock are sold to the public in this offering and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this offering).

As of June 30, 2011, we also had outstanding options to purchase 6,513,967 shares of our common stock at a weighted-average exercise price of $1.39 per share.

On January 7, 2011, we acquired all of the minority interest in BPS. We have issued 276,304 shares of our Series E preferred stock as consideration for this acquisition.

Upon the closing of this offering, all of the outstanding shares of our preferred stock will automatically convert into a total of shares of our common stock. No warrants to purchase shares of common stock remain outstanding as of June 30, 2011.

Common Stock

Voting Rights. Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our Board of Directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences. Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully paid and Nonassessable. All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

Upon the closing of this offering, all outstanding shares of preferred stock will have been automatically converted into shares of common stock. Following this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock.

Under the amended and restated certificate of incorporation, our Board of Directors will have the authority, without further action by the stockholders, to issue up to shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Under an amended and restated investor rights agreement, following the completion of this offering, the holders of an aggregate of shares of common stock, or their transferees, will have the right to require us to register their shares with the SEC so that those shares may be publicly resold, or to include their shares in any registration statement we file, subject to specified exemptions, conditions and limitations.

Beginning twelve months after the closing of this offering, subject to specified limitations, these stockholders may require that we register all or part of these securities for sale under the Securities Act on two occasions. In addition, these stockholders may from time to time make demand for registrations on Form S-3, a short form registration statement, when we are eligible to use this form.

If we register any of our common stock, either for our own account or for the account of other security holders, these stockholders are entitled to notice of the registration and to include their shares of common stock in the registration.

Other than in a demand registration, with specified exceptions, a holder's right to include shares in a registration is subject to the right of the underwriters to limit the number of shares included in the offering.

All fees, costs and expenses of any demand registrations and any registrations on Form S-3 will be paid by us, and all selling expenses, including underwriting discounts and commissions, will be paid by the holders of the securities being registered.

Delaware Anti-takeover Law and Certain Provisions of Our Amended and Restated Certificate of Incorporation and Bylaws

Delaware law. We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for this purpose shares owned by persons who are directors and also officers and shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock.

Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our Board of Directors to issue up to shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may only be removed for cause, which removal may be effected subject to any limitation imposed by law, by the holders of at least $66^{2}/_{3}\%$ of the voting power of our then outstanding capital stock entitled to vote generally at an election of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our Board of Directors into three classes with staggered, three-year terms;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose;
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our amended and restated bylaws only upon receiving at least $66^{2}/_{3}\%$ of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be BNY Mellon Shareowner Services.

NASDAQ Global Market

We have applied to have our common stock listed on the NASDAQ Global Market under the symbol "NLNK".

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Market sales of shares of our common stock after this offering and from time to time, and the availability of shares for future sale, may reduce the market price of our common stock. Sales of substantial amounts of our common stock, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to obtain capital, especially through an offering of equity securities.

Based on the number of shares of common stock outstanding as of June 30, 2011, upon completion of this offering, shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of options prior to the completion of this offering. All of the shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, unless held by our affiliates as that term is defined under Rule 144 under the Securities Act. The remaining shares of common stock outstanding upon the closing of this offering are restricted securities as defined under Rule 144 of the Securities Act. Restricted securities may be sold in the U.S. public market only if registered or if they qualify for an exemption from registration, including by reason of Rule 144 or 701 under the Securities Act, which rules are summarized below. These remaining shares will generally become available for sale in the public market as follows:

- restricted shares will be eligible for immediate sale upon the completion of this offering;
- approximately restricted shares will be eligible for sale in the public market 90 days after the date of this prospectus, subject to the volume, manner of sale and other limitations under Rule 144 and Rule 701; and
- approximately restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, which date may be extended in specified circumstances, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Additionally, of the 6,513,967 shares of common stock issuable upon exercise of options outstanding as of June 30, 2011, approximately 4,650,490 shares will be vested and eligible for sale 180 days after the date of this prospectus.

Rule 144

In general, under Rule 144 under the Securities Act of 1933, as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock to be sold for at least six months, would be entitled to sell an unlimited number of shares of our common stock, provided current public information about us is available. In addition, under Rule 144, a person who is not one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares of our common stock to be sold for at least one year, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months are entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below under "Underwriting" and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with some of the restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares under Rule 701. However, all of the Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" and will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Lock-up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders, optionholders and warrantholders, have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, we or they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock, subject to specified exceptions. Stifel, Nicolaus & Company, Incorporated and Canaccord Genuity Inc. may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs and is publicly announced; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period.

In this case, the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release of the material news or the occurrence of the material event.

The lock-up agreements signed by our securityholders generally permit them, among other customary exceptions, to make bona fide gifts to their immediate family, to transfer securities to trusts for their or their immediate family's benefit and, if the securityholder is a partnership, limited liability company or corporation, to transfer securities to its partners, members or stockholders. However, the recipients of these transfers must agree to be bound by the lock-up agreement for the remainder of the lock-up period.

Registration Rights

Upon the closing of this offering, the holders of an aggregate of shares of our common stock will have the right to require us to register their shares for resale under the Securities Act, beginning six months after the date of this prospectus. Registration of these shares for resale under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of such registration. Any sales of securities by these stockholders could

adversely affect the trading price of our common stock. These registration rights are described in more detail under the caption "Description of Capital Stock—Registration Rights."

Equity Incentive Plans

As of June 30, 2011, options to purchase an aggregate of 6,513,967 shares of our common stock were outstanding, of which 3,984,667 were vested and exercisable. Substantially all of the shares issuable upon the exercise of options are subject to the terms of the lock-up agreements with the underwriters. On October 29, 2010, 1,500,000 additional shares of common stock were added to the shares reserved for future issuance under our 2009 plan. This amount will be increased pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year. However, our Board of Directors will have the authority to designate a lesser number of shares by which the share reserve will be increased.

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our 2000 Equity Incentive Plan, 2009 Equity Incentive Plan, 2010 Non-Employee Directors' Stock Award Plan and 2010 Employee Stock Purchase Plan. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

CERTAIN U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the U.S. federal income and estate tax consequences to a non-U.S. holder (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income and estate tax consequences and does not address any tax consequences arising under any state, local or foreign tax laws or under other U.S. federal tax laws (such as gift tax laws). This discussion is based on the Internal Revenue Code of 1986, as amended (the "Code"), U.S. Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service (the "IRS"), all as in effect on the date of this offering. These authorities are subject to change, possibly retroactively, resulting in tax consequences different from those discussed below. No rulings have been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a different position concerning the tax consequences of a non-U.S. holder's purchase, ownership or disposition of our common stock or that any such position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase our common stock in this offering and who hold shares of our common stock as "capital assets" within the meaning of Code Section 1221 (generally, property held for investment). This discussion does not address all U.S. federal income tax or estate tax consequences that may be relevant to a non-U.S. holder in light of the holder's particular circumstances or to holders subject to special rules under the U.S. federal income tax laws, such as banks, financial institutions, U.S. expatriates, insurance companies, regulated investment companies, real estate investment trusts, "controlled foreign corporations," "passive foreign investment companies," dealers in securities or currencies, traders in securities, partnerships or other pass-through entities (or investors in such entities), persons subject to the alternative minimum tax, tax-exempt organizations and persons holding our common stock as part of a "straddle," "hedge," "conversion transaction" or other integrated transaction.

WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR OWN TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING GIFT TAX LAWS), AND ANY APPLICABLE TAX TREATIES.

For purposes of the U.S. federal income tax portion of this discussion, a "non-U.S. holder" is a beneficial owner of our common stock who is an individual, corporation, estate or trust for U.S. federal income tax purposes and who is not treated for U.S. federal income tax purposes as:

- an individual who is a citizen or resident of the United States;
- an entity treated as a corporation for U.S. federal income tax purposes that is created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a U.S. court is able to exercise primary supervision over its administration and one or more U.S. persons have authority to control all its substantial decisions or (ii) the trust was in existence on August 20, 1996, was treated as a U.S. person prior to that date, and validly elected to continue to be so treated.

A modified definition of non-U.S. holder applies for U.S. federal estate tax purposes.

If any entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and the activities of the

partnership. Partnerships and their partners should consult their tax advisors as to the tax consequences to them of the purchase, ownership and disposition of our common stock.

This discussion assumes that a non-U.S. holder will not hold our common stock in a manner that would subject the non-U.S. holder to the newly-enacted withholding tax discussed below under "New legislation relating to foreign accounts."

Distributions on our Common Stock

Payments on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a non-U.S. holder's adjusted tax basis in the common stock (determined on a share-by-share basis), but not below zero. Any remaining excess will be treated as capital gain from the sale of property as described below under "—Gain on Disposition of our common stock."

Dividends paid to a non-U.S. holder of our common stock that are not effectively connected with the holder's conduct of a U.S. trade or business generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or a lower rate specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying the holder's qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their own tax advisors regarding their possible entitlement to benefits under a relevant tax treaty.

If dividends paid on our common stock are effectively connected with a non-U.S. holder's U.S. trade or business, the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI or IRS Form W-8BEN, as applicable (or an applicable successor form) prior to the payment of the dividends.

Any dividends paid on our common stock that are effectively connected with a non-U.S. holder's U.S. trade or business generally will be subject to U.S. federal income tax on a net income basis in the same manner as if the holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of any effectively connected earnings and profits. Non-U.S. holders should consult their own tax advisors regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of our Common Stock

Subject to the discussion below regarding backup withholding, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States;
- the non-U.S. holder is an individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or

- our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation ("USRPHC") at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock (the "applicable period").

Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis in the same manner as if the holder were a resident of the United States. Non-U.S. holders that are foreign corporations also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of any effectively connected earnings and profits. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or a lower rate specified by an applicable tax treaty), but may be offset by U.S. source capital losses, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and we do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests, there can be no assurance that we are not currently or will not become a USRPHC in the future. In the event we are or become a USRPHC, as long as our common stock is regularly traded on an established securities market, our common stock will constitute a U.S. real property interest only with respect to a non-U.S. holder that actually or constructively holds more than 5% of our common stock at some time during the applicable period. Any taxable gain generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to such holder and the amount, if any, of tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

Backup withholding, currently at a rate of 28% (and scheduled to increase to 31% after 2012), generally will not apply to payments of dividends to a non-U.S. holder of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status (typically, by providing a valid IRS Form W-8BEN or W-8ECI) or an exemption is otherwise established.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through a non-U.S. office of a broker will not be subject to information reporting or backup withholding, except that information reporting (but generally not backup withholding) may apply to those payments if the broker does not have documentary evidence that the beneficial owner is a non-U.S. holder, an exemption is not otherwise established, and the broker is:

- a U.S. person;
- a controlled foreign corporation for U.S. federal income tax purposes;
- a foreign person 50% or more of whose gross income is effectively connected with a U.S. trade or business for a specified three-year period; or

- a foreign partnership if at any time during its tax year (1) one or more of its partners are U.S. persons who hold in the aggregate more than 50% of the income or capital interest in the partnership or (2) it is engaged in the conduct of a U.S. trade or business.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through the U.S. office of a broker generally will be subject to information reporting and backup withholding unless the non-U.S. holder certifies as to its non-U.S. status (such as by providing a valid IRS Form W-8BEN or W-8ECI) or otherwise establishes an exemption from information reporting and backup withholding.

Backup withholding is not an additional tax. Taxpayers may use amounts withheld as a credit against their U.S. federal income tax liability or may claim a refund if they timely provide certain information to the IRS.

New Legislation Relating to Foreign Accounts

Newly enacted legislation may impose withholding taxes on certain types of payments made to or through "foreign financial institutions" and certain other non-U.S. entities after December 31, 2012. The legislation imposes a 30% withholding tax on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign financial institution (whether holding stock for its own account or on behalf of its account holders/investors) unless the foreign financial institution enters into an agreement with the U.S. Treasury to among other things, undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. In addition, the legislation imposes a 30% withholding tax on the same types of payments to a foreign non-financial entity unless the entity certifies that it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner and satisfies certain other requirements. Prospective investors should consult their own tax advisors regarding this legislation.

Estate Tax

Common stock owned or treated as owned by an individual who is not a citizen or resident of the United States (as specifically defined for U.S. federal estate tax purposes) at the time of death is considered a U.S. situs asset includible in the individual's gross estate for U.S. federal estate tax purposes and therefore may be subject to U.S. federal estate tax, unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United States for federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be "non-U.S. holders" for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa. Prospective investors are urged to consult their tax advisors regarding the U.S. federal estate tax considerations of acquiring, holding, and disposing of common stock.

UNDERWRITING

Under the terms and subject to the conditions contained in an underwriting agreement dated , 2011 by and among us and the underwriters named below, the underwriters have agreed to purchase, we have agreed to sell to them, the number of shares of common stock indicated in the table below:

Underwriter	Number of Shares
Stifel, Nicolaus & Company, Incorporated	
Canaccord Genuity Inc.	
Robert W. Baird & Co. Incorporated	
Total	

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock offered by this prospectus if any are purchased, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

Commissions and Expenses

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus and to certain dealers at that price less a concession of not more than $ per share, of which up to $ per share may be reallowed to other dealers. After the initial offering, the public offering price, concession and reallowance to dealers may be changed.

The following table summarizes the underwriting discounts and commissions and the proceeds, before expenses, payable to us, both on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their overallotment option:

		Total	
	Per Share	Without Option	With Option
Public offering price			
Underwriting discounts and commissions			
Proceeds, before expenses, to us			

We estimate that the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $.

Over-Allotment Option

We have granted a 30-day option to the underwriters to purchase up to a total of additional shares of our common stock from us at the initial public offering price per share less the underwriting discounts and commissions per share, as set forth on the cover page of this prospectus, and less any dividends or distributions declared, paid or payable on the shares that the underwriters have agreed to purchase from us but that are not payable on such additional shares, to cover over-allotment, if

any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

Directed Share Program

At our request, the underwriters have reserved up to of the shares of common stock for sale at the initial public offering price to persons who are directors, officers or employees or who are otherwise associated with us, through a directed share program. The number of shares of common stock available for sale to the general public will be reduced by the number of directed shares purchased by participants in the directed share program. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares of common stock offered. Any shares purchased by our officers, directors, selling stockholders or other existing security holders in the directed share program will be subject to the 180-day lock-up period from the date of this prospectus, as described below.

Indemnification of Underwriters

The underwriting agreement provides that we will indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

We, all of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering, and the holders of all of our warrants and substantially all of our options outstanding prior to this offering, have agreed, subject to certain exceptions, that, without the prior written consent of Stifel, Nicolaus & Company, Incorporated and Canaccord Genuity Inc., we and they will not, during the period beginning on and including the date of this prospectus through and including the date that is the 180th day after the date of this prospectus, directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;
- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock; or
- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. Moreover, if:

- during the last 17 days of the lock-up period, we issue an earnings release or material news or a material event relating to us occurs; or
- prior to the expiration of the lock-up period, we announce that we will release earnings results or become aware that material news on a material event relating to us will occur during the 16-day period beginning on the last day of the lock-up period,

the restrictions described in the immediately preceding sentence will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, as the case may be, unless Stifel, Nicolaus & Company, Incorporated and Canaccord Genuity Inc. waive, in writing, that extension.

Stifel, Nicolaus & Company, Incorporated and Canaccord Genuity Inc. may, in their sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements. Any determination to release any shares or other securities subject to the lock-up agreements would be based on a number of factors at the time of determination, which may include the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares or other securities proposed to be sold or otherwise transferred and the timing, purpose and terms of the proposed sale or other transfer.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters of the offering, or by their affiliates. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by the underwriters is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters and should not be relied upon by investors.

No Public Market

We have applied to list our common stock on the NASDAQ Global Market under the symbol "NLNK," but there has been no public market for the shares prior to this offering. The offering price for the shares has been determined by us and the representatives, based on the following factors:

- the history and prospects for the industry in which we compete;
- our past and present operations;
- our historical results of operations;
- our prospects for future business and earning potential;
- our management;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of securities of generally comparable companies;
- the market capitalization and stages of development of other companies which we and the representatives believe to be comparable to us; and
- other factors deemed to be relevant.

We cannot assure you that the initial public offering price will correspond to the price of which our common stock will trade in the public market after this offering or that an active trading market for the common stock will develop and continue after this offering.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares of common stock is completed, Securities and Exchange rules may limit the underwriters from bidding for and purchasing shares of our common stock.

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or make short sales of our common stock and may purchase our common stock on the open market to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. The underwriters may close out any short position by purchasing shares in the open market or by exercising their overallotment option.

A short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in this offering. A "stabilizing bid" is a bid for or the purchase of common stock on behalf of the underwriters in the open market prior to the completion of this offering for the purpose of fixing or maintaining the price of the shares of common stock. A "syndicate covering transaction" is the bid for or purchase of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our shares or preventing or retarding a decline in the market price of our shares. As a result, the price of our shares may be higher than the price that might otherwise exist in the open market.

In connection with this offering, the underwriters may also engage in passive market making transactions in our common stock on the NASDAQ Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

Affiliations

In the future, the underwriters and their affiliates may provide various investment banking, commercial banking, financial advisory and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for their own accounts or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans.

Sales Outside the United States

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock, or the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither of this prospectus nor any other offering material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell common stock offered by this prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus (the "Shares") may not be

made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Notice to Prospective Investors in the United Kingdom

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospective Directive ("qualified investors") that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, (ii) who fall within Article 49(2)(a) to (d) of the Order or (iii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). The shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares will be engaged in only with, relevant persons. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

The distribution of this prospectus in the United Kingdom to anyone not falling within the above categories is not permitted and may contravene the Financial Services and Markets Act of 2000. No person falling outside those categories should treat this prospectus as constituting a promotion to him, or act on it for any purposes whatever. Recipients of this prospectus are advised that we, the underwriters and any other person that communicates this prospectus are not, as a result solely of communicating this prospectus, acting for or advising them and are not responsible for providing recipients of this prospectus with the protections which would be given to those who are clients of any aforementioned entities that is subject to the Financial Services Authority Rules.

Notice to Prospective Investors in France

The prospectus supplement and the accompanying prospectus (including any amendment, supplement or replacement thereto) have not been approved either by the *Autorité des marchés financiers* or by the

competent authority of another State that is a contracting party to the Agreement on the European Economic Area and notified to the *Autorité des marchés financiers*; no security has been offered or sold and will be offered or sold, directly or indirectly, to the public in France within the meaning of Article L. 411-1 of the French *Code Monétaire et Financier* except to permitted investors, or Permitted Investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (*investisseurs qualifiés*) acting for their own account and/or a limited circle of investors (*cercle restreint d'investisseurs*) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Articles L. 411-2, D. 411-1, D. 411-2, D. 411-4, D. 744-1, D. 754-1 and D. 764-1 of the French *Code Monétaire et Financier*; none of this prospectus supplement and the accompanying Prospectus or any other materials related to the offer or information contained therein relating to our securities has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any securities acquired by any Permitted Investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French *Code Monétaire et Financier* and applicable regulations thereunder.

Notice to Prospective Investors in Germany

This document has not been prepared in accordance with the requirements for a securities or sales prospectus under the German Securities Prospectus Act *(Wertpapierprospektgesetz)*, the German Sales Prospectus Act *(Verkaufsprospektgesetz)*, or the German Investment Act *(Investmentgesetz)*. Neither the German Federal Financial Services Supervisory Authority *(Bundesanstalt fur Finanzdienstleistungsaufsicht—BaFin)* nor any other German authority has been notified of the intention to distribute the securities in Germany. Consequently, the securities may not be distributed in Germany by way of public offering, public advertisement or in any similar manner AND THIS DOCUMENT AND ANY OTHER DOCUMENT RELATING TO THE OFFERING, AS WELL AS INFORMATION OR STATEMENTS CONTAINED THEREIN, MAY NOT BE SUPPLIED TO THE PUBLIC IN GERMANY OR USED IN CONNECTION WITH ANY OFFER FOR SUBSCRIPTION OF THE SECURITIES TO THE PUBLIC IN GERMANY OR ANY OTHER MEANS OF PUBLIC MARKETING. The securities are being offered and sold in Germany only to qualified investors which are referred to in Section 3, paragraph 2 no. 1, in connection with Section 2, no. 6, of the German Securities Prospectus Act. This document is strictly for use of the person who has received it. It may not be forwarded to other persons or published in Germany.

Notice to Prospective Investors in Switzerland

The securities which are the subject of the offering contemplated by this prospectus may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. None of this prospectus or any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

None of this prospectus or any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the securities.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Broomfield, Colorado. The underwriters are being represented by Cahill Gordon & Reindel LLP, New York, New York.

EXPERTS

The consolidated financial statements of NewLink Genetics Corporation and subsidiary (a development stage enterprise) as of December 31, 2010 and 2009, and for each of the years in the three-year period ended December 31, 2010, and for the period from June 4, 1999 (inception), through December 31, 2010, have been included herein in reliance upon the report of KPMG LLP, an independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2010, financial statements refers to the adoption of new guidance on the presentation and disclosure of noncontrolling interests.

The common stock valuations as of December 31, 2007, 2008 and 2009, March 31, 2010, June 30, 2010, September 30, 2010 and December 31, 2010 have been included herein in reliance upon reports of the Mentor Group, Inc., an independent valuation specialist, and upon the authority of said firm as valuation experts.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to NewLink Genetics Inc. and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.linkp.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

The Board of Directors
NewLink Genetics Corporation and Subsidiary:

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiary (a development stage enterprise) (the Company) as of December 31, 2009 and 2010, and the related consolidated statements of operations, equity (deficit), and cash flows for each of the years in the three year period ended December 31, 2010 and for the period from June 4, 1999 (inception) through December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NewLink Genetics Corporation and subsidiary (a development stage enterprise) as of December 31, 2009 and 2010, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2010, and for the period from June 4, 1999 (inception) through December 31, 2010, in conformity with U.S. generally accepted accounting principles.

As discussed in note 2 to the consolidated financial statements, the Company has adopted guidance on the presentation and disclosure of noncontrolling interests as of January 1, 2009.

/s/ KPMG LLP

February 25, 2011, except as to note 3, which is as of September 7, 2011
Des Moines, Iowa

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31, 2009	December 31, 2010	June 30, 2011 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 15,217	$ 10,572	$ 9,550
Certificates of deposit	1,992	2,269	250
Prepaid expenses	110	959	1,599
State research and development credit receivable	170	230	370
Interest receivable	68	8	—
Other receivables	1,341	604	329
Total current assets	18,898	14,642	12,098
Leasehold improvements and equipment:			
Leasehold improvements	2,293	3,804	3,804
Computer equipment	430	691	695
Lab equipment	1,765	3,165	3,290
Total leasehold improvements and equipment	4,488	7,660	7,789
Less accumulated depreciation and amortization	(1,569)	(2,224)	(2,572)
Leasehold improvements and equipment, net	2,919	5,436	5,217
Notes receivable from related parties	850	—	—
Total assets	$ 22,667	$ 20,078	$ 17,315

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Balance Sheets (Continued)

(In thousands, except share and per share data)

	December 31, 2009	December 31, 2010	June 30, 2011 (unaudited)	Pro forma Equity at June 30, 2011 (unaudited) (Note 2)
Liabilities and Equity				
Current liabilities:				
Accounts payable	$ 1,080	$ 552	$ 313	
Accrued expenses	1,176	1,554	1,383	
Deferred rent	947	951	932	
Notes payable to Iowa Department of Economic Development	—	—	6,000	
Obligations under capital leases	35	116	122	
Current portion of long term debt	—	91	93	
Deposits on restricted shares	3	1	—	
Total current liabilities	3,241	3,265	8,843	
Long term liabilities:				
Notes payable to Iowa Department of Economic Development	6,000	6,000	—	
Notes payable to Iowa State University Research Park	—	642	594	
Notes payable to City of Ames	—	300	300	
Obligations under capital leases	78	145	151	
Total long-term liabilities	6,078	7,087	1,045	
Total liabilities	9,319	10,352	9,888	
Redeemable preferred stock, $0.01 par value:				
Authorized shares—14,327,777 at December 31, 2009, 15,327,777 at December 31, 2010 and June 30, 2011 and 0 at June 30, 2011 pro forma; issued and outstanding shares—13,200,436 at December 31, 2009, 13,417,435 at December 31, 2010 and 13,850,113 at June 30, 2011 and 0 at June 30, 2011 pro forma; liquidation preference—$54,136 at December 31, 2009, $61,782 at December 31, 2010 and $75,303 at June 30, 2011 and $0 at June 30, 2011 pro forma	54,134	61,745	75,272	—
Equity:				
Blank check preferred stock, $0.01 par value: Authorized shares—1,388,889 at December 31, 2009 and 2010 and June 30, 2011 pro forma; issued and outstanding shares—0 at December 31, 2009 and 2010 and June 30, 2011 pro forma	—	—	—	—
Series A preferred stock, $0.01 par value: Authorized shares—450,000 at December 31, 2009 and 2010 and June 30, 2011 and 0 at June 30, 2011 pro forma; issued and outstanding shares—420,000 at December 31, 2009 and 2010 and June 30, 2011 and 0 at June 30, 2011 pro forma; liquidation preference—$1,050 at December 31, 2009 and 2010 and June 30, 2011 and $0 at June 30, 2011 pro forma	1,030	1,030	1,030	—
Common stock, $0.01 par value: Authorized shares—32,000,000 at December 31, 2009 and 38,833,334 at December 31, 2010 and June 30, 2011 and June 30, 2011 pro forma; issued and outstanding shares—6,671,401 at December 31, 2009, 7,618,973 at December 31, 2010, 7,662,222 at June 30, 2011 and 24,819,660 at June 30, 2011 pro forma	67	76	77	248
Additional paid-in capital	2,979	7,334	2,728	78,859
Notes receivable for common stock	(38)	(13)	—	—
Deficit accumulated during the development stage	(47,176)	(63,389)	(71,680)	(71,680)
Total NewLink Genetics shareholders' (deficit) equity	(43,138)	(54,962)	(67,845)	7,427
Equity attributable to noncontrolling interests	2,352	2,943	—	—
Total (deficit) equity	(40,786)	(52,019)	(67,845)	7,427
Commitments				
Total liabilities and deficit	$ 22,667	$ 20,078	$ 17,315	

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Operations

(In thousands, except share and per share data)

	Year Ended December 31,			Cumulative from June 4, 1999 (inception) through December 31, 2010
	2008	2009	2010	
Grant revenue	$ 633	$ 934	$ 2,079	$ 3,845
Operating expenses:				
Research and development	5,790	7,578	12,666	46,063
General and administrative	3,938	3,705	6,074	24,156
Total operating expenses	9,728	11,283	18,740	70,219
Loss from operations	(9,095)	(10,349)	(16,661)	(66,374)
Other income and expense:				
Miscellaneous income	42	19	71	353
Forgiveness of debt	—	—	—	449
Interest income	213	132	75	1,742
Interest expense	(2)	(9)	(47)	(101)
Other income (expense), net	253	142	99	2,443
Net loss	(8,842)	(10,207)	(16,562)	(63,931)
Less net loss attributable to noncontrolling interest	—	233	349	582
Net loss attributable to NewLink	$ (8,842)	$ (9,974)	$ (16,213)	$ (63,349)
Net loss attributable to common stockholders	$ (8,842)	$ (9,974)	$ (16,213)	$ (63,349)
Net loss per share, basic and diluted	$ (1.35)	$ (1.50)	$ (2.30)	
Weighted-average shares outstanding, basic and diluted	6,541,520	6,635,986	7,039,895	
Pro forma net loss per share, basic and diluted (unaudited) (note 2)			$	
Weighted-average pro forma shares outstanding, basic and diluted (unaudited) (note 2)				

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Operations

(In thousands, except share and per share data)

(unaudited)

	Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30, 2011
	2010	2011	
Grant revenue	$ 730	$ 1,141	$ 4,986
Operating expenses:			
Research and development	5,696	6,975	53,038
General and administrative	2,284	2,452	26,608
Total operating expenses	7,980	9,427	79,646
Loss from operations	(7,250)	(8,286)	(74,660)
Other income and expense:			
Miscellaneous income	8	1	354
Forgiveness of debt	—	—	449
Interest income	23	8	1,750
Interest expense	(19)	(15)	(116)
Other income (expense), net	12	(6)	2,437
Net loss	(7,238)	(8,292)	(72,223)
Less net loss attributable to noncontrolling interest	151	1	583
Net loss attributable to NewLink	(7,087)	(8,291)	(71,640)
Net loss attributable to common stockholders	$ (7,087)	$ (8,291)	$ (71,640)
Net loss per share, basic and diluted	$ (1.06)	$ (1.08)	
Weighted-average shares outstanding, basic and diluted	6,709,969	7,647,231	
Pro forma net loss per share, basic and diluted		$	
Weighted-average pro forma shares outstanding, basic and diluted			

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Equity (Deficit)

(In thousands, except share and per share data)

	Preferred Stock Series A	Common Stock: Number of Common Shares Outstanding	Common Stock: Common Stock	Common Stock: Additional Paid-in Capital	Common Stock: Notes Receivable For Common Stock	Common Stock: Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non-Controlling Interest	Total Equity (Deficit)
Balance at June 4, 1999	$ —	—	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Initial stock issuance (November 11, 1999)	—	4,000,000	40	—	(13)	—	—	27	—	27
Net loss	—	—	—	—	—	—	(64)	(64)	—	(64)
Balance at December 31, 1999	—	4,000,000	40	—	(13)	—	(64)	(37)	—	(37)
Loan payment	—	—	—	—	13	—	—	13	—	13
Common stock issuance (April 18, 2000)	—	1,389,200	12	125	(92)	—	—	45	—	45
Common stock issuance (June 13, 2000)	—	53,000	1	13	(12)	—	—	2	—	2
Issuance of 420,000 shares of Series A preferred stock (net of offering costs) (August 29, 2000)	989	—	—	—	—	—	—	989	—	989
Net loss	—	—	—	—	—	—	(236)	(236)	—	(236)
Balance at December 31, 2000	989	5,442,200	53	138	(104)	—	(300)	776	—	776
Repurchase of common stock and settlement of notes receivable (January 29, 2001)	—	(276,793)	—	—	18	(33)	—	(15)	—	(15)
Issuance of common stock (August 2, 2001)	—	200,000	2	48	—	—	—	50	—	50
Deemed dividend due to sale of Series AA preferred shares (September 26, 2001) (note 4)	41	—	—	—	—	—	(41)	—	—	—
Net loss	—	—	—	—	—	—	(1,448)	(1,448)	—	(1,448)
Balance at December 31, 2001	1,030	5,365,407	55	186	(86)	(33)	(1,789)	(637)	—	(637)
Receipt of payment on note receivable (April 5 and October 5, 2002)	—	—	—	—	2	—	—	2	—	2
Issuance of common stock from exercise of stock options (July 26, 2002)	—	50,000	1	12	—	—	—	13	—	13
Receipt of payment on note receivable (September 4, 2002)	—	—	—	—	31	—	—	31	—	31
Issuance of dividend paid in common stock (October 18, 2002)	—	44,097	1	(1)	—	—	—	—	—	—
Issuance of stock options to nonemployees	—	—	—	14	—	—	—	14	—	14
Accretion of redemption feature of preferred stock	—	—	—	(6)	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(2,253)	(2,253)	—	(2,253)
Balance at December 31, 2002	1,030	5,459,504	57	205	(53)	(33)	(4,042)	(2,836)	—	(2,836)
Issuance of common stock for compensation (March 20, 2003)	—	20,000	1	45	—	—	—	46	—	46
Receipt of payment on note receivable (January 1, April 4, July 9, and September 29, 2003)	—	—	—	—	7	—	—	7	—	7
Issuance of common stock from exercise of warrants (various dates through March 2003)	—	494,628	4	1,108	—	—	—	1,112	—	1,112
Issuance of dividend paid in common stock	—	44,097	1	(1)	—	—	—	—	—	—
Issuance of stock options	—	—	—	15	—	—	—	15	—	15
Accretion of redemption feature of preferred stock	—	—	—	(5)	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(2,979)	(2,979)	—	(2,979)
Balance at December 31, 2003	1,030	6,018,229	63	1,367	(46)	(33)	(7,021)	(4,640)	—	(4,640)
Receipt of payment on note receivable (February 25, 2004 and July 15, 2004)	—	—	—	—	5	—	—	5	—	5
Issuance of stock options	—	—	—	57	—	—	—	57	—	57
Accretion of redemption feature of preferred stock	—	—	—	(5)	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	—	(3,669)	(3,669)	—	(3,669)
Balance at December 31, 2004	$ 1,030	6,018,229	$ 63	$ 1,419	$ (41)	$ (33)	$ (10,690)	$ (8,252)	$ —	$ (8,252)

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Equity (Deficit) (Continued)

(In thousands, except share and per share data)

	Preferred Stock Series A	Common Stock: Number of Common Shares Outstanding	Common Stock: Common Stock	Common Stock: Additional Paid-in Capital	Common Stock: Notes Receivable For Common Stock	Common Stock: Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non-Controlling Interest	Total Equity (Deficit)
Balance at December 31, 2004 (brought forward)	$ 1,030	6,018,229	$ 63	$ 1,419	$ (41)	$ (33)	$ (10,690)	$ (8,252)	$ —	$ (8,252)
Receipt of payment on note receivable	—	—	—	—	1	—	—	1	—	1
Issuance of stock options	—	—	—	2	—	—	—	2	—	2
Issuance of dividend paid in common stock (September 23, 2005)	—	88,190	1	(1)	—	—	—	—	—	—
Issuance of common stock for OncoRx acquisition (June 21, 2005)	—	130,102	1	353	—	—	—	354	—	354
Issuance of common stock to consultants (April 4 and June 1, 2005)	—	18,787	—	51	—	—	—	51	—	51
Issuance of 593,247 shares of Series BB preferred stock (net of offering costs of $36,114) (January and February 2005)	—	—	—	—	—	—	—	—	—	—
Accretion of redemption feature of preferred stock	—	—	—	(82)	—	—	—	(82)	—	(82)
Issuance of subsidiary preferred stock	—	—	—	—	—	—	—	—	2,278	2,278
Net loss	—	—	—	—	—	—	(4,770)	(4,770)	—	(4,770)
Balance at December 31, 2005	1,030	6,255,308	65	1,742	(40)	(33)	(15,460)	(12,696)	2,278	(10,418)
Stock compensation	—	—	—	22	—	—	—	22	—	22
Issuance of common stock for OncoRx acquisition (March 22, 2006)	—	130,102	1	129	—	—	—	130	—	130
Issuance of dividend paid in common stock (September 25, 2006)	—	44,091	1	(1)	—	—	—	—	—	—
Issuance of subsidiary preferred stock	—	—	—	—	—	—	—	—	250	250
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	7	7
Accretion of redemption feature of preferred stock	—	—	—	(4)	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(5,318)	(5,318)	—	(5,318)
Balance at December 31, 2006	1,030	6,429,501	67	$ 1,888	$ (40)	$ (33)	$ (20,778)	$ (17,866)	$ 2,535	$ (15,331)
Stock compensation	—	—	—	58	—	—	—	58	—	58
Exercise of stock options	—	32,500	—	12	—	—	—	12	—	12
Receipt of payment on note receivable	—	—	—	—	2	—	—	2	—	2
Issuance of common stock for license milestone (August 2, 2007)	—	25,000	—	—	—	—	—	—	—	—
Issuance of dividend paid in common stock	—	44,091	1	(1)	—	—	—	—	—	—
Retire treasury stock	—	—	(3)	(30)	—	33	—	—	—	—
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	8	8
Net loss	—	—	—	—	—	—	(7,582)	(7,582)	—	(7,582)
Balance at December 31, 2007	1,030	6,531,092	65	$ 1,927	$ (38)	$ —	$ (28,360)	$ (25,376)	$ 2,543	$ (22,833)
Stock compensation	—	—	—	86	—	—	—	86	—	86
Exercise of stock options	—	32,125	—	19	—	—	—	19	—	19
Issuance of common stock for license milestone (September 8, 2008)	—	5,000	—	5	—	—	—	5	—	5
Issuance of dividend paid in common stock	—	44,099	1	(1)	—	—	—	—	—	—
Issuance of subsidiary common stock, net of deposits	—	—	—	—	—	—	—	—	(1)	(1)
Net loss	—	—	—	—	—	—	(8,842)	(8,842)	—	(8,842)
Balance at December 31, 2008	$ 1,030	6,612,316	$ 66	$ 2,036	$ (38)	$ —	$ (37,202)	$ (34,108)	$ 2,542	$ (31,566)

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Equity (Deficit) (Continued)

(In thousands, except share and per share data)

	Preferred Stock Series A	Common Stock: Number of Common Shares Outstanding	Common Stock: Common Stock	Common Stock: Additional Paid-in Capital	Common Stock: Notes Receivable For Common Stock	Common Stock: Treasury Stock	Deficit Accumulated During the Development Stage	Total NewLink Genetics Shareholders' Equity	Non-Controlling Interest	Total Equity (Deficit)
Balance at December 31, 2008 (brought forward)	$ 1,030	6,612,316	$ 66	$ 2,036	$ (38)	$ —	$ (37,202)	$ (34,108)	$ 2,542	$ (31,566)
Stock compensation	—	—	—	929	—	—	—	929	—	929
Exercise of stock options	—	14,990	—	15	—	—	—	15	—	15
Issuance of dividend paid in common stock	—	44,095	1	(1)	—	—	—	—	—	—
Issuance of subsidiary common stock net of deposits	—	—	—	—	—	—	—	—	3	3
Issuance of 30,000 shares of subsidiary Series B preferred stock (November 16, 2009)	—	—	—	—	—	—	—	—	40	40
Net loss	—	—	—	—	—	—	(9,974)	(9,974)	(233)	(10,207)
Balance at December 31, 2009	1,030	6,671,401	67	$ 2,979	$ (38)	$ —	$ (47,176)	$ (43,138)	$ 2,352	$ (40,786)
Stock compensation	—	—	—	1,525	—	—	—	1,525	—	1,525
Exercise of stock options	—	297,303	3	79	—	—	—	82	—	82
Exercise of warrants for common stock	—	375,000	3	1,997	—	—	—	2,000	—	2,000
Receipt of payment and forgiveness of note receivable	—	—	—	—	25	—	—	25	121	146
Issuance of common stock for OncoRX acquisition (July 29, 2010)	—	364,285	3	816	—	—	—	819	—	819
Issuance of common stock for license termination (September 3, 2010)	—	50,000	1	200	—	—	—	201	—	201
Issuance of dividend paid in common stock	—	44,095	1	(1)	—	—	—	—	—	—
Accretion of redemption feature of preferred stock	—	—	—	(2)	—	—	—	(2)	—	(2)
Conversion of preferred stock to common stock	—	31,321	—	114	—	—	—	114	—	114
Repurchase and retirement of common stock (December 20, 2010)	—	(214,432)	(2)	(373)	—	—	—	(375)	(94)	(469)
Issuance of subsidiary common stock net of deposits	—	—	—	—	—	—	—	—	2	2
Issuance of 555,930 shares of subsidiary Series B Preferred Stock (September 7, 2010)	—	—	—	—	—	—	—	—	911	911
Net loss	—	—	—	—	—	—	(16,213)	(16,213)	(349)	(16,562)
Balance at December 31, 2010	$ 1,030	7,618,973	$ 76	$ 7,334	$ (13)	$ —	$ (63,389)	$ (54,962)	$ 2,943	$ (52,019)
Stock compensation	—	25,000	—	977	—	—	—	977	—	977
Exercise of stock options	—	119	—	—	—	—	—	—	—	—
Receipt of payment on note receivable	—	—	—	—	13	—	—	13	—	13
Conversion of preferred stock to common stock	—	18,130	1	114	—	—	—	115	—	115
Accretion of redemption feature of preferred stock	—	—	—	(5)	—	—	—	(5)	—	(5)
Acquisition of noncontrolling interest	—	—	—	(5,692)	—	—	—	(5,692)	(2,942)	(8,634)
Net loss	—	—	—	—	—	—	(8,291)	(8,291)	(1)	(8,292)
Balance at June 30, 2011 (unaudited)	$ 1,030	7,662,222	$ 77	$ 2,728	$ —	$ —	$ (71,680)	$ (67,845)	$ —	$ (67,845)

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

(In thousands, except share and per share data)

	Year Ended December 31,			Cumulative from June 4, 1999 (inception) through December 31, 2010
	2008	2009	2010	
Cash Flows From Development Activities				
Net loss	$ (8,842)	$ (10,207)	$ (16,562)	$ (63,931)
Adjustments to reconcile net loss to net cash used in development activities:				
Share-based compensation	86	929	1,525	2,804
Depreciation and amortization	294	303	655	2,274
In-process research and development expenses—OncoRx	5	—	819	1,428
Issuance of common stock for license termination	—	—	201	201
Forgiveness of debt	—	—	—	(449)
Forgiveness of notes receivable from related parties	—	—	350	350
Changes in operating assets and liabilities:				
Prepaid expenses	(38)	(60)	(849)	(959)
State research and development credit receivable	(222)	329	(60)	(230)
Interest due on notes receivable	(25)	(23)	60	(8)
Other receivables	—	(1,341)	737	(604)
Accounts payable	(361)	(271)	(528)	(197)
Accrued expenses and deferred rent	218	1,201	382	2,505
Net cash used in development activities	(8,885)	(9,140)	(13,270)	(56,816)
Cash Flows From Investing Activities				
Purchase of investments	(1,850)	(142)	(277)	(8,800)
Sale of investments	—	—	—	6,531
Notes receivable from related parties	(850)	—	500	(350)
Purchase of equipment	(427)	(1,403)	(2,932)	(6,488)
Cash paid for OncoRx	—	—	—	(120)
Net cash provided by (used in) investing activities	(3,127)	(1,545)	(2,709)	(9,227)
Cash Flows From Financing Activities				
Cash received from noncontrolling interest investment	—	40	911	3,479
Issuance of common stock	—	—	—	192
Issuance of common stock from exercise of stock options	19	15	82	140
Issuance of common stock from exercise of warrants	—	—	2,000	3,113
Repurchase of common stock	—	—	(468)	(501)
Repayments (advances) of notes receivable for common stock	—	—	25	(13)
Proceeds (repurchases) from subsidiary common stock option exercise and notes receivable	(4)	—	121	141
Proceeds from preferred stock (including deposits)	2,039	19,580	7,723	62,743
Transfer (to) from restricted cash	15,880	—	—	—
Proceeds from notes payable	—	—	1,100	7,759
Principal payments on debt	—	—	(67)	(277)
Payments under capital lease obligations	(4)	(9)	(93)	(161)
Net cash provided by financing activities	17,930	19,626	11,334	76,615
Net (decrease) increase in cash and cash equivalents	5,918	8,941	(4,645)	10,572
Cash and cash equivalents at beginning of period	358	6,276	15,217	—
Cash and cash equivalents at end of period	$ 6,276	$ 15,217	$ 10,572	$ 10,572
Supplemental disclosure of cash flows information:				
Cash paid for interest	$ 2	$ 9	$ 44	$ 62
Noncash financing and investing activities:				
Accretion on redeemable preferred stock	—	—	2	105
Purchased leasehold improvements and equipment in accounts payable	—	749	—	769
Common stock issued to acquire goods or services	5	—	932	1,654
Issuance of common stock dividend to Series AA preferred shareholders	1	1	1	5
Assets acquired under capital lease	12	114	282	462

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Consolidated Statements of Cash Flows

(In thousands, except share and per share data)

(unaudited)

	Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30, 2011
	2010	2011	
Cash Flows From Development Activities			
Net loss	$ (7,238)	$ (8,292)	$ (72,223)
Adjustments to reconcile net loss to net cash used in development activities:			
Share-based compensation	809	979	3,783
Depreciation and amortization	266	348	2,622
In-process research and development expenses—OncoRx	—	—	1,428
In-process research and development expenses—Reconstitute	—	—	201
Forgiveness of debt	—	—	(449)
Forgiveness of notes receivable from related parties	—	—	350
Changes in operating assets and liabilities:			
Prepaid expenses	1,176	(429)	(1,388)
State research and development credit receivable	(45)	(140)	(370)
Interest due on notes receivable	16	8	—
Other receivables	—	65	(539)
Accounts payable	(285)	(240)	(437)
Accrued expenses and deferred rent	(259)	(190)	2,315
Net cash used in development activities	(5,560)	(7,891)	(64,707)
Cash Flows From Investing Activities			
Purchase of investments	(250)	—	(8,800)
Sale of investments	—	2,019	8,550
Notes receivable from related parties	500	—	(350)
Purchase of equipment	(2,765)	(54)	(6,542)
Cash paid for OncoRx	—	—	(120)
Net cash provided by (used in) investing activities	(2,515)	1,965	(7,262)
Cash Flows From Financing Activities			
Cash received from noncontrolling interest investment	304	—	3,479
Issuance of common stock	—	—	192
Issuance of common stock from exercise of stock options	19	—	140
Issuance of common stock from exercise of warrants	—	—	3,113
Repurchase of common stock	—	—	(501)
Repayments (advances) of notes receivable for common stock	—	13	—
Proceeds from subsidiary common stock option exercise	62	—	141
Proceeds from preferred stock (including deposits)	—	5,000	67,743
Proceeds from notes payable	1,100	—	7,759
Principal payments on debt	(22)	(48)	(325)
Payments under capital lease obligations	(33)	(61)	(222)
Net cash provided by financing activities	1,430	4,904	81,519
Net (decrease) increase in cash and cash equivalents	(6,645)	(1,022)	9,550
Cash and cash equivalents at beginning of period	15,217	10,572	—
Cash and cash equivalents at end of period	$ 8,572	$ 9,550	$ 9,550
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 17	$ 15	$ 77
Noncash financing and investing activities:			
Accretion on redeemable preferred stock	—	5	110
Purchased leasehold improvements and equipment in accounts payable	39	0	769
Common stock issued to shareholders of OncoRx as part of acquisition	—	—	1,654
Issuance of common stock dividend to Series AA preferred shareholders	—	—	5
Assets acquired under capital lease	—	75	537

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

(Information as of June 30, 2011, for the six-month periods ended June 30, 2011 and 2010, and for the cumulative period June 4, 1999 (inception) through June 30, 2011 is unaudited)

1. Description of Business and Development Stage Activities

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed for the purpose of developing treatments for cancer and other diseases. NewLink initiated operations in April of 2000, which primarily consist of research and development.

In 2005, NewLink created a wholly owned subsidiary, BioProtection Systems Corporation (BPS). NewLink contributed certain licensing agreements and other intangible assets for BPS to create vaccines against potential biological terror threats. During 2006, BPS granted options to the founders of NewLink and employees and consultants of BPS to acquire shares of BPS common stock. A portion of these options were exercised during 2008 and 2009, which diluted NewLink's ownership. At December 31, 2009, NewLink owned 72% of BPS and on an as-if-converted-to-common-stock basis, NewLink's ownership of BPS would be 63%. At December 31, 2010, NewLink owned 71% of BPS and on an as-if-converted-to-common-stock basis, NewLink's ownership of BPS would be 64%. On January 7, 2011, NewLink acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of NewLink with BPS, with BPS as the surviving corporation resulting in NewLink's owning all the outstanding capital stock of BPS. See note 20.

NewLink and its subsidiary (the Company) are development stage enterprises and are devoting substantially all of their efforts toward research and development.

The Company has never earned revenue from sales of its drugs under development. The Company has, from June 4, 1999 (inception) through December 31, 2010 generated a cumulative deficit of $62.7 million. The accompanying financial statements for the year ended December 31, 2010 have been prepared assuming the Company will continue as a going concern. The generation of additional financing will be necessary for the Company to continue operations in the future. During the years ended December 31, 2010 and 2009, the Company received financing of $9.8 million and $19.6 million, respectively. During the year ended December 31, 2010, BPS received financing of $900,000.

The Company incurred a net loss of $8.3 million for the six months ended June 30, 2011, and from inception through June 30, 2011 has generated a cumulative deficit of $71.7 million. The Company has managed its liquidity needs during its development stage to date through a series of capital market transactions, including raising $5 million in June 2011 from the sale of shares of the Company's Series E preferred stock. The accompanying financial statements as of and for the six months ended June 30, 2011 have been prepared assuming the Company will continue as a going concern. The Company anticipates that its existing capital resources as of June 30, 2011 will be adequate to satisfy its liquidity requirements through June 30, 2012. If available liquidity is not sufficient to meet the Company's operating obligations as they come due, management's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs, including obtaining an extension of the due date of the $6 million note due to the Iowa Department of Economic Development (see note 7), may have a material adverse affect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Notes to Consolidated Financial Statements (Continued)

(Information as of June 30, 2011, for the six-month periods ended June 30, 2011 and 2010, and for the cumulative period June 4, 1999 (inception) through June 30, 2011 is unaudited)

The Company's Board of Directors has approved the filing of a registration statement on Form S-1 with respect to a proposed initial public offering (IPO) of its common stock. There is no assurance that additional financing will be consummated or obtained in sufficient amounts or on acceptable terms to meet the Company's needs.

2. Significant Accounting Policies

(a) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles (U.S. GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(b) Principles of Consolidation

The consolidated financial statements include the financial statements of NewLink and its majority-owned subsidiary. All significant intercompany balances and transactions have been eliminated in consolidation.

(c) Cash and Cash Equivalents

For the purposes of the consolidated statements of cash flows, the Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents. Cash equivalents of $9.6 million, $10.6 million and $15.2 million at June 30, 2011, December 31, 2010 and December 31, 2009, respectively, consist of money market accounts. Cash received for deposits on sales of equity securities is classified as restricted cash until the shares are issued. No cash is restricted at June 30, 2011, December 31, 2010 and December 31, 2009.

(d) Certificates of Deposit

Certificates of deposit have original maturities of greater than three months. Certificates of deposit are classified as held-to-maturity with due dates through 2011 and are presented at amortized cost, which approximates fair value.

(e) Prepaid Expenses

Prepaid expenses includes costs directly attributable to the Company's offering of its equity securities. In accordance with FASB Accounting Standards Codification (ASC) 340-10, *Other Assets and Deferred Costs*, these costs are deferred and capitalized as part of prepaid expenses. Costs attributable to the equity offerings will be charged against the proceeds of the offering once completed.

(f) Leasehold Improvements and Equipment

Leasehold improvements and equipment are stated at cost. Equipment under capital leases is stated at the present value of minimum lease payments.

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Notes to Consolidated Financial Statements (Continued)

(Information as of June 30, 2011, for the six-month periods ended June 30, 2011 and 2010, and for the cumulative period June 4, 1999 (inception) through June 30, 2011 is unaudited)

Depreciation on all leasehold improvements and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years and lab equipment has useful lives of three to seven years.

During 2009, the Company added leasehold improvements to a new facility under an operating lease. As part of the lease, the lessor approved a tenant improvement allowance of $943,000 for improvements made to the facility. This amount was receivable from the lessor at December 31, 2009 and recorded in other receivables. The receivable was subsequently collected from lessor in January 2010. The offsetting amount is recorded as deferred rent on the financial statements and will reduce rent expense over the remaining term of the lease. The Company incurred costs in excess of the tenant improvement allowance during 2009.

(g) Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future net undiscounted cash flows expected to be generated by the asset group, primarily relating to proceeds for selling the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

(h) Revenue Recognition

The Company receives payments from government entities under its grants and contracts with the National Institute of Health and the Department of Defense. These agreements provide the Company cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. Revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the cost reimbursement was provided have been met and we have only perfunctory obligations outstanding. During the six months ended June 30, 2011 and years ended December 31, 2010, 2009, 2008, from inception through December 31, 2010 and since inception, the Company has earned $1.1 million, $2.1 million, $934,000, $633,000, $3.8 million, and $5.0 million in grant revenue, respectively.

(i) Expenses Accrued Under Contractual Arrangements with Third Parties; Accrued Clinical Expenses

The Company estimates its accrued expenses through a process of reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed and estimating the level of service performed and the associated cost incurred for the service that may not be invoiced from the provider. The estimates of accrued expenses as of each balance sheet date are based on facts and circumstances known at that time. Such estimates are periodically confirmed with the service providers to verify accuracy.

The Company bases its expenses related to clinical trials on estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research

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organizations that conduct and manage clinical trials on behalf of the Company. The Company does not expect its estimates to be materially different from amounts actually incurred.

(j) Pro Forma Stockholders' Equity (Unaudited)

In October 2010, the Company's Board of Directors authorized the filing of a registration statement with the Securities and Exchange Commission (SEC) to sell shares of its common stock to the public in an IPO. The Company filed an initial S-1 registration statement with the SEC on December 21, 2010. All of the Company's convertible preferred stock outstanding at June 30, 2011 will convert into 17,157,438 shares of common stock upon completion of the IPO. The Company's Series AA, AAA, B, BB, C and D convertible preferred stock have a current conversion ratio of one share of common stock for every share of convertible preferred stock. The Company's Series A convertible preferred stock has a current conversion ratio of 1.389 shares of common stock for every share of convertible preferred stock. The Company's Series E preferred stock will convert into the number of shares of common stock obtained by dividing $31.25 by the Series E conversion price. The Series E conversion price is currently $6.25 and the number of common shares issuable upon conversion in connection with this offering has been calculated based on this price. If the Company closes this initial public offering on or before December 31, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of common stock are sold to the public in this initial public offering and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with this initial public offering). Because the number of common shares that will be issued upon conversion of the Series E preferred stock depends upon the initial public offering price per share in this offering, the actual number of common shares issuable upon such conversion will likely differ from the respective number of shares set forth above. Pro forma equity includes the effect of this transaction as if it occurred on June 30, 2011. Pro forma net loss per share and weighted-average pro forma shares outstanding include the effect of this transaction as if it occurred on January 1, 2010.

(k) Research and Development

Research and development costs are expensed as incurred. Certain research and development expenses are refundable from the state of Iowa without regard to income. State research and development credits of $140,000, $230,000, $170,000, $272,000, $1.6 million, and $1.7 million at June 30, 2011, December 31, 2010, 2009, and 2008, from inception through December 31, 2010 and since inception through June 30, 2011, respectively, are reflected as a reduction of research and development expenses on the accompanying consolidated statements of operations.

(l) Patents

The Company generally applies for patent protection on processes and products. Patent application costs are expensed as incurred as a component of research and development expense, as recoverability of such expenditures is uncertain.

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(m) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operating results in the period that includes the enactment date.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. As of June 30, 2011 and December 31, 2010 and 2009, the Company has not recognized any uncertain tax positions.

(n) Stock Option Valuation

The Company is required to estimate the grant-date fair value of stock options issued to employees and recognize this cost over the period these awards vest. The Company estimates the fair value of each option granted using the Black-Scholes option pricing model. Generally, the Company has issued employee awards with a graded vesting schedule that vest over time. For these awards, the Company records compensation cost on a straight-line basis over the vesting period for the entire award.

The Company has issued awards to nonemployee consultants and advisors. All grants to nonemployees are valued using the same fair value method that the Company uses for grants to employees. The compensation cost recognized on these awards is determined on the later of the vesting of the award or completion of services by the nonemployee.

Following is a description of the inputs for the Black-Scholes model:

Exercise Price

The Company's stock options are granted with an exercise price as determined by the Board of Directors.

Expected Term (in Years)

The expected term of a stock option is the period of time for which the option is expected to be outstanding. The Company has a large number of options outstanding and has no secondary market. Therefore, the Company used the simplified method under current SEC guidance to estimate the expected term. The simplified method uses the midpoint between the fully vested date and the forfeiture date as the expected term for the employee and nonemployee director grants. For nonemployee grants, the contractual life of the option is used.

Risk-Free Interest Rate

The Company uses the average yield on current U.S. Treasury instruments with terms that approximate the expected term of the stock options being valued.

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Expected Dividend Yield

The expected dividend yield for all of the Company's stock option grants is 0%, as the Company has not declared a cash dividend since inception and has no plans to declare a dividend.

Expected Volatility

Since the Company is a privately held firm, the estimated future expected volatility for each stock option valuation utilizes volatility rates of similar publicly traded companies considered to be in the same peer group.

Forfeitures

The share-based compensation expense has been reduced for estimated forfeitures. The estimated forfeiture rate is based on historical experience of the Company's option plan, which the Company expects to continue at the current level, and any adjustments in the forfeiture rate in the future will result in a cumulative adjustment in the period that this estimate is changed. Ultimately, the total compensation expense recognized for any given stock-based award over its vesting period will only be for those shares that actually vest.

(o) Noncontrolling Interest

The Company has consolidated 100% of the assets, liabilities, and income from subsidiaries for which the Company has a majority voting interest. The Company has recorded a noncontrolling interest in subsidiaries on the consolidated balance sheets and noncontrolling interest in net loss of subsidiaries on the consolidated statements of operations representing the noncontrolling interest's equity and their proportionate share of net loss.

In December 2007, the Financial Accounting Standards Board (FASB) issued new authoritative guidance on the presentation and disclosures of noncontrolling interests in consolidated financial statements to improve the relevance, comparability, and transparency. The Company adopted the authoritative guidance on noncontrolling interests on January 1, 2009. As a result of the adoption, the Company now allocates a portion of the loss from its subsidiary to the noncontrolling interest. This creates a deficit balance from operations, which was not allowed under previous accounting literature. The amount allocated to the noncontrolling interest was $1,300 during the six months ended June 30, 2011 and $349,000 and $233,000 during the years ended December 31, 2010 and 2009, respectively. Had the Company continued to apply previous accounting literature, the loss for the six months ended June 30, 2011 and the years ended December 31, 2010 and December 31, 2009 would be $8.3 million, $16.6 million and $10.2 million, respectively, as none of the loss would be allocated to the noncontrolling interest as it would create a deficit balance. The noncontrolling interest was eliminated on January 7, 2011. See note 20.

(p) Segments

The Company operates in one segment. NewLink and its subsidiary BPS conduct research and development activities based from facilities located in Ames, Iowa. The Ames location also includes corporate headquarters for NewLink and BPS. The companies conduct preclinical and clinical research in

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the biopharmaceutical industry. Management uses cash flow as the primary measure to manage its business and does not segment its business for internal reporting or decision-making.

(q) Financial Instruments and Concentrations of Credit Risk

The fair values of cash and cash equivalents, certificates of deposit, prepaid expenses, receivables, accounts payable, and accrued liabilities, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and certificates of deposit. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high quality securities such as money market funds. The fair value of notes payable and capital lease obligations was $6.1 million, $7.3 million, and $7.3 million as of December 31, 2009 and 2010, and June 30, 2011, respectively.

(r) Unaudited Interim Financial Data

The accompanying balance sheet as of June 30, 2011, statements of operations and of cash flows for the six months ended June 30, 2010 and 2011 and for the period from June 4, 1999 (inception) through June 30, 2011 and the statements of equity (deficit) for the six months ended June 30, 2011 and for the period from June 4, 1999 (inception) through June 30, 2011 are unaudited. The unaudited interim financial statements have been prepared on a basis consistent with the audited financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) considered necessary to state fairly the Company's financial position as of June 30, 2011 and the results of operations and cash flows for the six months ended June 30, 2010 and 2011 and for the period from June 4, 1999 (inception) through June 30, 2011. The financial data and other information disclosed in these notes to the financial statements related to the six month periods ended June 30, 2010 and 2011 and for the period from June 4, 1999 (inception) through June 30, 2010 are unaudited. The results for the six months ended June 30, 2011 are not necessarily indicative of the results to be expected for the year ending December 31, 2011 or for any other interim period.

(s) Recent Accounting Pronouncements

In April 2009, FASB issued guidance that expands the fair value disclosures required for financial instruments to interim reporting periods for publicly traded companies, including disclosure of the significant assumptions used to estimate the fair value of financial instruments. We adopted this guidance effective June 30, 2010. The adoption did not impact our financial position or results of operations.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The amended guidance requires disclosure of transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy, including the reasons and the timing of the transfers and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of the assets and liabilities measured under Level 3 of the fair value measurement hierarchy. The Company adopted the new disclosure requirements on January 1, 2010, except for the requirement concerning gross presentation of Level 3 activity, which is effective for fiscal

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years beginning after December 15, 2010. The adoption of the Level 1 and Level 2 disclosure guidance did not have an impact on the Company's consolidated financial position or results of operations.

In recent exposure drafts, the International Accounting Standards Board (IASB) and the FASB proposed a new approach to the accounting for leases. From a lessee's perspective, the exposure drafts propose to abolish the distinction between operating and finance/capital leases. In its place, a right-of-use model would be used. This proposal, as currently written, would require the lessee to recognize an asset for its right to use the underlying leased asset and a liability for its obligation to make lease payments. This would lead to an increase in assets and liabilities for leases currently classified as an operating lease and could also lead to a change in timing as to when the expense is recognized. This exposure draft is not yet finalized.

3. Immaterial Corrections

The Company has corrected immaterial errors in the historical financial statements related to the stock compensation and research and development expenses. The errors related to the fair value and volatility assumptions used in the stock compensation calculations, the allocation of these expenses to research and development activities, adjusting certain research and development expenses, and the correction of other classification errors within research and development expenses and general and administrative expenses. In accordance with the SEC's Staff Accounting Bulletin (SAB) No. 99, *Materiality*, and SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, management evaluated the materiality of the errors from qualitative and quantitative perspectives and concluded that the errors were immaterial to the Company's historical financial statements. Consequently, the Company has revised its historical financial statements for the years ended December 31, 2008 and 2009 as noted in the table below. The Company has also revised the disclosure of the inputs to the Black-Scholes model for estimating the fair value of stock options to disclose the assumptions now used in the calculation. The impact on beginning deficit accumulated during the

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development stage and additional paid-in capital for 2008 was $318 and $54, respectively. The errors also had an impact on the cumulative balances from inception as of December 31, 2009.

2008	As previously reported	Adjustments	As adjusted
Research and development	$ 5,451	$ 339	$ 5,790
General and administrative	4,598	(660)	3,938
Net loss	(9,162)	(320)	(8,842)
Net loss per share	(1.40)		(1.35)
Additional paid-in capital	2,090	(54)	2,036
Deficit accumulated during the development stage	(37,520)	318	(37,202)
2009			
Research and development	$ 5,559	$ 2,019	$ 7,578
General and administrative	5,192	(1,487)	3,705
Net loss	(9,442)	532	(9,974)
Net loss per share	(1.42)		(1.50)
Additional paid-in capital	2,765	214	2,979
Deficit accumulated during the development stage	(46,962)	(214)	(47,176)

Subsequent to the issuance of the 2010 financial statements, the Company identified errors related to stock compensation, research and development expenses, and general and administrative expenses in the 2010 financial statements. The errors related to the fair value and volatility assumptions used in the stock compensation calculations, the allocation of these expenses to research and development activities, the recognition of certain general and administrative expenses, and the correction of other classification errors within research and development expenses. Management evaluated the materiality of the errors from qualitative and quantitative perspectives in accordance with SAB No. 99 and concluded that the errors were immaterial to the Company's historical financial statements. The Company has revised its 2010 financial statements as noted in the table below. The errors also had an impact on the cumulative balances from inception as of December 31, 2010.

	As previously reported	Adjustments	As adjusted
Prepaid expenses	$ 1,020	$ 61	$ 959
Additional paid-in capital	6,713	621	7,334
Deficit accumulated during the development stage	(62,707)	682	(63,389)
Research and development	13,249	(583)	12,666
General and administrative	5,023	1,051	6,074
Net loss	(15,745)	468	(16,213)
Net loss per share	(2.24)		(2.30)

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4. Acquisition of OncoRx Corporation

On June 21, 2005, NewLink acquired all of the outstanding shares of OncoRx Corporation (OncoRx) in order to gain access to certain small molecule technologies. NewLink provided the following consideration to the OncoRx shareholders:

- 780,611 shares of NewLink common stock payable in four installments. The first installment was 130,102 shares at closing. The second, third, and fourth installments result in the delivery of 130,102, 260,204, and 260,203 shares, respectively, conditional upon the achievement of certain development milestones as described in the purchase agreement.
- Cash consideration of $120,000 at closing.

During 2005, the cash and first installment of shares noted above were delivered to OncoRx. During 2006, NewLink issued the second installment of 130,102 shares of common stock with a fair value of $130,000. All cash and stock consideration paid to the OncoRx shareholders has been recorded as research and development expense at fair value when delivered as there is no alternative use for the acquired research and development activities. There were no other assets or liabilities of OncoRx at the date of acquisition. Upon the achievement of the development milestones, the Company will record the fair value of the third and fourth installments of common stock issued as research and development expense.

On July 29, 2010, the Company entered into an amendment of the stock purchase agreement with OncoRx to reduce the remaining shares payable under the third and fourth installments by accelerating the payment of such installments to the effective date of the amendment. In consideration for the accelerated stock payment, the Company received a 30% discount on the remaining shares payable, reducing total shares payable under the agreement by 156,122 shares. A total of 364,285 shares were issued with total fair value of $819,000. Through this acquisition, the Company acquired technology related to its IDO pathway inhibitor product candidates, subject to a licensing agreement with the Lankenau Institute for Medical Research.

5. Notes Receivable for Common Stock

Notes receivable for common stock at June 30, 2011 and December 31, 2010 and 2009 were $0, $13,000 and $38,000, respectively. The notes were issued in connection with the sale of common stock to officers of the Company and, accordingly, are shown as a reduction of shareholders' equity (deficit). All of the notes are secured by the common stock and are guaranteed by the officer's personal assets. The outstanding notes for NewLink common stock were due in April 2005 and were subsequently extended for an additional five years through April 2010. Subsequent to April 2010, a decision was made to forgive a portion of these notes, subject to Board approval. All of the notes for NewLink common stock bear interest at rates from 5.00% to 6.71%, payable annually in arrears. Effective as of July 2, 2010, $25,000 of the notes and accrued interest of $10,000 were forgiven and a bonus of $12,000 was granted to cover the resulting tax liability. To offset the forgiveness and the bonus payment, outstanding options to purchase Company common stock were modified to increase the aggregate exercise price by an amount equal to the amount of the forgiveness plus the bonus paid.

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6. Leases

(a) Capital Leases

The following is an analysis of the leased property under capital leases by major class (in thousands):

	Asset balances at December 31		Asset balances at June 30
Class of property	2009	2010	2011
Lab equipment	$ 126	$ 409	$ 484
Leasehold improvements	27	27	27
Total property under capital leases	153	436	511
Less accumulated depreciation and amortization	72	67	101
Capital leased assets, net	$ 81	$ 369	$ 410

The depreciation and amortization reflected above has been recorded as depreciation and amortization expense in these consolidated financial statements.

The following is a schedule by years of the future minimum lease payments under capital leases together with the present value of the net minimum lease payments as of December 31, 2010 (in thousands):

Year ending December 31:	
2011	$ 135
2012	114
2013	40
Total minimum lease payments	289
Less amount representing interest	28
Present value of net minimum lease payments	$ 261

The present value of net minimum lease payments as of December 31, 2009 is reflected in the balance sheet as current and long-term obligations under capital leases of $35,000 and $78,000, respectively. The present value of net minimum lease payments as of December 31, 2010 is reflected in the balance sheet as current and long-term obligations under capital leases of $116,000 and $145,000, respectively. The present value of net minimum lease payments as of June 30, 2011 is reflected in the balance sheet as current and long-term obligations under capital leases of $122,000 and $151,000, respectively.

(b) Operating Leases

The Company has noncancelable facilities operating leases that expired at various times between February 2009 and June 2009, which are now being leased on a month-to-month basis. In addition, the Company entered into a new lease for additional space in October 2009 expiring in 2015. Under the terms of the lease, the Company has the option to extend the lease for three additional five-year periods upon

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the same terms as the base lease. The Company also leases laboratory space from one of its licensors. Lease expense is recognized on a straight-line basis. Rental expense for operating leases during the six month period ending June 30, 2011 and the years ended December 31, 2010, 2009, 2008, from inception through December 31, 2010, and since inception through June 30, 2011 was $322,000, $601,000, $294,000, $396,000, $2.0 million and $2.3 million respectively.

Future minimum lease payments under the noncancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2010 are as follows (in thousands):

Year ending December 31:	
2011	$ 266
2012	269
2013	271
2014	271
2015	23
	$ 1,100

7. Long-Term Debt

March 2005 Iowa Department of Economic Development Loan

In March 2005, the Company entered into a $6.0 million forgivable loan agreement with the Iowa Department of Economic Development (IDED). Under the agreement, in the absence of default, there will be no principal or interest payments due until the completion date for the project, which is March 18, 2012, under the current one-year extension granted by the IDED. The project is to provide assistance to the Company for research and product development activities at its Iowa State University Research Park facility. The project calls for the creation of 315 positions and retention of 35 positions with total project expenditures of $189.9 million for clinical trials, research and development activities, building construction, equipment purchases, and other working capital needs.

If, as of March 18, 2012, which is the current project completion date under the agreement, the IDED determines the Company has fulfilled all the job creation and maintenance terms and project expenditure requirements of the loan agreement, the loan will be forgiven. However, on the project completion date the Company will be required to repay the greater of approximately $17,000 for each of the 350 jobs it fails to create and maintain as of that date or a percentage of the $6.0 million advanced under the agreement equal to the percentage of any shortfall in its obligation to expend $189.9 million of project expenditures. Five years following the project completion date, the Company will be required to repay approximately $17,000 for each of the 350 jobs the IDED determines it fails to maintain as of that date. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note including 6% interest per annum beginning at the date of default.

The Company has not currently fulfilled the requirements for loan forgiveness under this agreement. Absent an amendment granted by the IDED, the Company would have to repay up to $4.7 million on or after March 18, 2012. There is no guarantee that the IDED will agree to further extend the completion

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date under the agreement. If the amounts under the loan become due in March 2012, it would likely have a material adverse effect on the Company's cash position.

Under the agreement, the Company is obligated to pay a minimum of 0.25% royalties on all gross revenues of its products with a cumulative maximum royalty amount due of $3.2 million. Royalties the Company pays will first offset amounts the Company is required to repay for amounts of the loan not forgiven and then go toward reducing the total cumulative royalty to be paid. The Company is also obligated to maintain its business in the State of Iowa while amounts remain outstanding under the loan. Substantially all of the Company's assets are pledged against this loan and the Company is required to submit audited financial statements within 90 days of year-end. The Company has failed to meet this covenant each year and has obtained a waiver from the IDED each year.

The original project completion date for the project was March 18, 2010 and was initially extended to March 18, 2011 and currently to March 18, 2012 by amendments to the agreement approved by the IDED.

2009 Iowa State University Research Park Loan

In 2009, the Company executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000. The note represents amounts owed by the Company to ISURP for certain improvements that were made to facilities the Company leases from ISURP. The principal and interest owed under the note is amortized over an eight-year period. Interest is payable monthly under this promissory note, initially at a rate of 3.0% per annum and increasing to 5.0% per annum after five years from the date the improvements were completed. ISURP may accelerate all amounts owed under the note upon an event of default, including the Company's uncured material breach of the terms of the note or the lease or upon early termination of the lease. In the event of a default under the note, amounts owed under the note will bear interest at 8.0% per annum. No amounts were outstanding under this note as of December 31, 2009. The balance outstanding under this note at December 31, 2010 was $733,000. The balance outstanding under this note at June 30, 2011 is $687,000.

March 2010 City of Ames Forgivable Loan

In March 2010, the Company entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provides the Company with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015.

The project calls for the Company to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or maintain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, the Company has failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, the Company will be required to repay approximately $3,100 per job not created or retained following the respective date. As of June 30, 2011, $300,000 of the total $400,000 forgivable loan was advanced to the

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Company with the final $100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

8. Common Stock

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the NewLink stockholders. Subject to preferences applicable to outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the NewLink Board of Directors.

NewLink and its major investors have a right of first refusal with respect to certain sales of shares by existing stockholders. NewLink's major investors have a right of first refusal to acquire certain equity securities issued by NewLink. These rights expire with an IPO.

In the event of liquidation, dissolution, or winding up of NewLink, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

On January 7, 2011, the Shareholders approved an amendment to NewLink's Restated Certificate of Incorporation granting the Board of Directors authority to approve a reverse split of shares of issued and outstanding common stock between 1.5-for-1 and 3.0-for-1.

9. Subsidiary Common Stock and Common Stock Preferences

Subject to preferences applicable to outstanding preferred stock, the holders of BPS common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the BPS Board of Directors. BPS has issued two classes of common stock: Series A common stock and Series B common stock. All shares of Series A common stock are held by NewLink. The holders of BPS Series A and Series B common stock are entitled to one vote per share on all BPS matters to be voted upon by BPS's stockholders.

In the event of any liquidation, dissolution, or winding up of BPS, whether voluntary or involuntary, the holders of Series A common stock will be entitled to receive $0.10 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution, before any payment of any amount to holders of the Series B common stock. In the event of liquidation, dissolution, or winding up of BPS, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities subject to prior distribution rights of the preferred stock.

On January 7, 2011, NewLink acquired all of the outstanding shares of BPS Series B common stock. See note 20 and note 21.

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10. Preferred Stock

NewLink's Amended and Restated Certificate of Incorporation authorizes the issuance of 17,166,666 shares of preferred stock, $0.01 par value. The NewLink Board of Directors has the authority to issue the preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights subject to approval of outstanding preferred series shareholders. The following is a summary of all preferred stock issued by NewLink and outstanding at June 30, 2011 and December 31, 2010 and 2009:

		as of June 30, 2011 (in thousands, except share and per share data)			
	Issue Price per Share	Shares Authorized	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	$ 2.50	450,000	420,000	$ 1,050	$ 1,030
Series AA	1.80	1,250,000	1,217,175	2,191	2,191
Series AAA	2.25	377,777	377,410	849	849
Series B	2.50	3,200,000	2,191,193	5,478	5,478
Series BB	4.25	2,000,000	1,883,337	8,004	8,004
Series C	5.00	6,000,000	6,000,000	30,000	30,000
Series D	5.00	1,500,000	1,500,000	7,500	7,500
Series E	31.25	1,000,000	680,998	21,281	21,250
Blank Check Preferred	—	1,388,889	—	—	—
Total			14,270,113	$ 76,353	$ 76,302

		as of December 31, 2010 (in thousands, except share and per share data)			
	Issue Price per Share	Shares Authorized	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	$ 2.50	450,000	420,000	$ 1,050	$ 1,030
Series AA	1.80	1,250,000	1,217,175	2,191	2,191
Series AAA	2.25	377,777	377,410	849	849
Series B	2.50	3,200,000	2,191,193	5,478	5,478
Series BB	4.25	2,000,000	1,883,337	8,004	8,004
Series C	5.00	6,000,000	6,000,000	30,000	30,000
Series D	5.00	1,500,000	1,500,000	7,500	7,500
Series E	31.25	1,000,000	248,320	7,760	7,723
Blank Check Preferred	—	1,388,889	—	—	—
Total			13,837,435	$ 62,832	$ 62,775

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		as of December 31, 2009 (in thousands, except share and per share data)			
	Issue Price per Share	Shares Authorized	Issued and Outstanding Shares	Liquidation Preference	Carrying Value
Series A	$ 2.50	450,000	420,000	$ 1,050	$ 1,030
Series AA	1.80	1,250,000	1,224,967	2,205	2,205
Series AAA	2.25	377,777	377,410	849	847
Series B	2.50	3,200,000	2,191,193	5,478	5,478
Series BB	4.25	2,000,000	1,906,866	8,104	8,104
Series C	5.00	6,000,000	6,000,000	30,000	30,000
Series D	5.00	1,500,000	1,500,000	7,500	7,500
Blank Check Preferred	—	1,388,889	—	—	—
Total			13,620,436	$ 55,186	$ 55,164

On January 7, 2011, NewLink acquired all of the minority interest in BPS. See note 20 and. On June 20, 2011, the Company issued and sold to an investor 160,000 shares of Series E preferred stock at a purchase price of $31.25 per share, for aggregate consideration of $5.0 million (unaudited).

Between December 1, 2010 and December 13, 2010, the Company issued and sold to investors an aggregate of 248,320 shares of Series E preferred stock at a purchase price of $31.25 per share, for aggregate consideration of $7.8 million. The related offering costs of $37,000 were charged as an offset to the proceeds. The carrying value of the Series E preferred stock will be accreted to the liquidation amount by the date the shares are available to be redeemed. Each share of NewLink Series E preferred stock will convert into the number of shares of NewLink Common Stock obtained by dividing $31.25 by the NewLink Series E conversion price. The NewLink Series E conversion price is currently $6.25. If NewLink closes an IPO on or before December 31, 2011, the NewLink Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of NewLink's Common Stock are sold to the public in the IPO and (B) 0.85 (as adjusted appropriately to reflect any changes to the NewLink Series E conversion price occurring prior to any such adjustment occurring in connection with an IPO). The Company will use the midpoint of the IPO price range, once it is established, in order to estimate the number of shares of NewLink Common Stock issuable upon conversion of the NewLink Series E preferred stock.

On July 17, 2009, NewLink issued 1,500,000 shares of Series D convertible preferred stock at $5.00 per share for net proceeds of $7.5 million. The related offering costs were not significant and were charged to expense. NewLink also issued warrants to purchase 375,000 shares of common stock at $7.20 per share in conjunction with the issuance of Series D shares. On October 21, 2010, a stockholder exercised the warrant for 375,000 shares of common stock at an aggregate purchase price of $2.0 million. The exercise price of the warrant was reduced from $7.20 per share to $5.33 per share in 2010 in exchange for the holder's agreement to exercise the warrant at that time.

During 2009, NewLink collected $12.1 million for the sale of 2,413,379 shares of NewLink Series C preferred stock and $7.5 million for the sale of 1,500,000 shares of NewLink Series D preferred stock.

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Following is a summary of all redeemable preferred stock issuances through June 30, 2011:

	Redeemable Preferred Stock						
	Series AA	Series AAA	Series B	Series BB	Series C	Series D	Series E
Balance at June 4, 1999	$ —	$ —	$ —	$ —	$ —	$ —	$ —
No activity in 1999	—	—	—	—	—	—	—
Balance at December 31, 1999	—	—	—	—	—	—	—
No activity in 2000	—	—	—	—	—	—	—
Balance at December 31, 2000	—	—	—	—	—	—	—
Issuance of 1,224,967 shares of Series AA preferred stock (net of offering costs) (September 26, 2001)	2,179	—	—	—	—	—	—
Balance at December 31, 2001	2,179	—	—	—	—	—	—
Issuance of 377,410 shares of Series AAA preferred stock (net of offering costs) (January 21, 2002)	—	847	—	—	—	—	—
Accretion of redemption feature of preferred stock	6	—	—	—	—	—	—
Balance at December 31, 2002	2,185	847	—	—	—	—	—
Issuance of 2,191,193 shares of Series B preferred stock (net of offering costs) (February 7, 2003)	—	—	5,436	—	—	—	—
Accretion of redemption feature of preferred stock	6	—	—	—	—	—	—
Balance at December 31, 2003	2,191	847	5,436	—	—	—	—
Issuance of 1,313,619 shares of Series BB preferred stock (net of offering costs and receivables of $706,005) (December 27, 2004)	—	—	—	4,877	—	—	—
Accretion of redemption feature of preferred stock	5	—	—	—	—	—	—
Balance at December 31, 2004	2,196	847	5,436	4,877	—	—	—
Issuance of 593,247 shares of Series BB preferred stock (net of offering costs of $36,114) (January and February 2005)	—	—	—	3,192	—	—	—
Accretion of redemption feature of preferred stock	5	—	42	35	—	—	—
Balance at December 31, 2005	2,201	847	5,478	8,104	—	—	—
Accretion of redemption feature of preferred stock	4	—	—	—	—	—	—
Balance at December 31, 2006	2,205	847	5,478	8,104	—	—	—
No activity in 2007	—	—	—	—	—	—	—
Balance at December 31, 2007	2,205	847	5,478	8,104	—	—	—
Issuance of 3,586,621 shares of Series C preferred stock (net of offering costs of $13,530) (February through October 2008)	—	—	—	—	17,920	—	—
Balance at December 31, 2008	2,205	847	5,478	8,104	17,920	—	—
Issuance of 2,413,379 shares of Series C preferred stock (July through October 2009)	—	—	—	—	12,080	—	—
Issuance of 1,500,000 shares of Series D preferred stock (July 17, 2009)	—	—	—	—	—	7,500	—
Balance at December 31, 2009	2,205	847	5,478	8,104	30,000	7,500	—
Issuance of 248,320 shares of Series E preferred stock (net of offering costs) (December 1 through December 13, 2010)	—	—	—	—	—	—	7,723
Accretion of redemption feature of preferred stock	—	2	—	—	—	—	—
Conversion of preferred stock to common stock	(14)	—	—	(100)	—	—	—
Balance at December 31, 2010	2,191	849	5,478	8,004	30,000	7,500	7,723
Issuance of 436,304 shares of Series E preferred stock (January 7, 2011 and June 20, 2011)	—	—	—	—	—	—	13,635
Accretion of redemption feature of preferred stock	—	—	—	—	—	—	5
Conversion of preferred stock to common stock	—	—	—	—	—	—	(113)
Balance at June 30, 2011 (unaudited)	$ 2,191	$ 849	$ 5,478	$ 8,004	$ 30,000	$ 7,500	$ 21,250

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Prior to the acquisition by NewLink of the minority interest in BPS described in note 20, BPS had authority to issue stand-alone preferred stock to outside investors as discussed in note 12. The following is a summary of all preferred stock issued by BPS and outstanding at December 31, 2010:

Original issue	Date(s) issued	Shares issued	Offering price
Series A	January-February 2006	1,444,721	$1.75
Series B	2009-2010	2,341,644	$1.40-$1.75

11. Preferred Stock Preferences

Following is a summary of the preferences relating to the various series of NewLink preferred stock:

(a) Voting Rights

The Series A, AA, AAA, B, BB, C, D and E (collectively, the Series Preferred) vote on an as-if-converted-to-common-stock basis (one vote per share, except for Series A, which receives 1.389 votes per share pursuant to the conversion rights discussed below). Any action taken by the Board of Directors or others that would impact the holders of Series AA, B, BB, C, D or E shares must be approved by a majority of the outstanding shares held by Series AA, B, BB, C, D or E shareholders.

(b) Dividend Rights

Series A, AAA, B, BB, C, D and E stockholders, in preference to holders of common stock, are entitled to receive a noncumulative cash dividend of 8% of the original issue price per annum, payable only when, as, and if declared by the Board of Directors.

Series AA stockholders, in preference to holders of common stock, are entitled to receive a cumulative stock dividend of 0.036 shares of common stock for each outstanding share of Series AA. The dividend is paid at least annually. Dividends shall accrue monthly, and unpaid dividends shall be paid upon conversion of the Series AA to common stock. A total of 36,746, 14,683 and 14,683 shares of common stock are accrued for dividends on the Series AA stock as of June 30, 2011 and December 31, 2010 and 2009, respectively.

(c) Conversion Rights

The Series Preferred will automatically convert into common stock immediately upon the closing of an IPO of common stock pursuant to an effective registration statement filed by NewLink under the Securities Act of 1933 that generates aggregate gross proceeds of not less than $20.0 million. The Series Preferred may also convert to common stock upon a vote of action by a majority of the holders of the Series Preferred voting together as a single class on an as-if converted basis, or at the option of the holders. Persons holding 20% of NewLink 's common stock on an as-if converted basis can request NewLink file a registration statement.

Each share of Series A preferred stock will convert into 1.389 shares of NewLink Common Stock; each share of Series AA, AAA, B, C and D preferred stock will convert into one share of NewLink

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Common Stock; and each share of Series E preferred stock will convert into the number of shares of NewLink Common Stock obtained by dividing $31.25 by the Series E conversion price. The Series E conversion price is currently $6.25. If the Company closes an IPO on or before December 31, 2011, the Series E conversion price will automatically be adjusted to a price equal to the product of (A) the price at which shares of NewLink's Common Stock are sold to the public in the IPO and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E conversion price occurring prior to any such adjustment occurring in connection with the IPO). The Series Preferred are subject to weighted average ratchet antidilutive protection if NewLink issues shares at a price below the offering price for each series. In addition, these securities are subject to proportional adjustments for stock splits, stock dividends, recapitalizations, and other distributions of common stock of NewLink.

(d) Liquidation Preferences

In the event of any liquidation, dissolution, or winding up of NewLink, whether voluntary or involuntary, the holders of Series C, Series D and Series E will be entitled to receive $5.00 per share, $5.00 per share and $31.25 per share, respectively, plus any declared and unpaid dividends out of the assets of NewLink available for distribution before any payment of any amount to holders of the Series A, AA, AAA, B, BB (collectively, the Junior Preferred), or holders of common stock. If the assets available for distribution are insufficient to pay the holders of Series C, Series D and Series E preferred stock, then such holders will share ratably in any distribution of the assets of NewLink in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After payment of the full liquidation to the Series C, Series D and Series E holders, the holders of the Junior Preferred will be entitled to receive $2.50, $1.80, $2.25, $2.50, $4.25, respectively, per share plus any declared and unpaid dividends out of the assets of NewLink available for distribution before any payment of any amount to holders of NewLink common stock. If the assets available for distribution are insufficient to pay the holders of Junior Preferred, then such holders will share ratably in any distribution of the assets of NewLink in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After the payment of the full liquidation preference of the Series Preferred, the assets of NewLink legally available for distribution, if any, shall be distributed ratably to the holders of the common stock and Series Preferred on an as-if-converted-to-common-stock basis until such time as the holders of Series A, AA, AAA, and B have received an aggregate amount equal to three times the original issue price ($28,704,210 at June 30, 2011 and December 31, 2010 and $28,746,287 at December 31, 2009), the holders of the Series BB have received an aggregate amount equal to two times the original issue price ($16,008,365 at June 30, 2011 and December 31, 2010 and $16,208,361 at December 31, 2009). Thereafter, the remaining assets of NewLink legally available for distribution, if any, shall be distributed ratably to the holders of the common stock.

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(e) Additional Preferences

Redemption

If a majority of the outstanding shares of Series AA, B, BB, C, D and E vote to have NewLink redeem its stock, it must do so in three equal installments beginning on September 30, 2014, provided that NewLink receives 60 days' notice. Redemption price shall equal original sale price plus any declared and unpaid dividends on Series Preferred. NewLink is required on or prior to the redemption date to deposit the funds in trust with a bank or trust company.

Warrants

Warrants to purchase 375,000 shares of common stock at $7.20 per share were issued to Series D Preferred stockholders in conjunction with the purchase of NewLink preferred stock in July of 2009. The warrants were exercised on October 21, 2010, at an aggregate purchase price of $2.0 million. The exercise price of the warrant was reduced in exchange for the holder's agreement to exercise the warrant at that time. NewLink computed the fair value of the warrants at issuance using the Black-Scholes model and determined the fair value of the warrants was *de minimis*.

Right of First Refusal

NewLink's major investors have a right of first refusal to acquire certain equity securities issued by NewLink. These rights expire with an IPO.

Registration Rights

Under an amended and restated investor rights agreement, following an IPO, certain holders of NewLink common stock will have the right to require NewLink to register their shares with the SEC so that those shares may be publicly resold, or to include those shares in any registration statement NewLink files, subject to specified exemptions, conditions and limitations.

12. Subsidiary Preferred Stock Preferences (See note 20)

During 2009 and 2010, BPS issued 555,930 shares of Series B preferred stock at $1.75 per share for an aggregate consideration of $970,000. In December 2010, in connection with the merger of BPS with NewLink, BPS issued 1,785,714 shares of Series B preferred stock to NewLink at $1.40 per share for an aggregate consideration of $2.5 million.

During 2006, BPS issued 1,444,721 shares of Series A preferred stock. All deposits received prior to issuance of the shares were considered restricted until the shares of Series A preferred stock were issued. In July 2009, shareholders authorized the issuance of an additional 3,055,279 shares of BPS Series B preferred stock. Prior to the acquisition, BPS's amended Certificate of Incorporation authorized the issuance of 4,500,000 shares of preferred stock at $0.01 par value. The Board of Directors of BPS has the authority to issue the preferred stock in one or more series and to fix the voting power and such

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designations, preferences, and rights subject to approval of outstanding preferred series shareholders. The following preferences are in place related to the BPS Series A and B preferred stock:

(a) Voting Rights

The BPS Series A and B preferred stock vote on an as-if-converted-to-common-stock basis (one vote per share). Any action taken by the Board of Directors of BPS or others that would impact the holders of BPS Series A and B preferred stock must be approved by a majority of the outstanding shares held by BPS Series A and B shareholders.

(b) Conversion Rights

The BPS Series A and B preferred stock will automatically convert into BPS common stock immediately upon the closing of an IPO of BPS common stock, pursuant to an effective registration statement filed by BPS under the Securities Act of 1933 that generates aggregate gross proceeds of not less than $4.00 per common share and $10.0 million in aggregate. BPS Series A and B preferred stock may automatically convert upon a vote of action by the class or at the option of the holder.

(c) Liquidation Preferences

In the event of any liquidation, dissolution, or winding up of BPS, whether voluntary or involuntary, the holders of BPS Series B preferred stock will be entitled to receive $1.75 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution before any payment of any amount to holders of BPS Series A preferred stock or BPS common stock. If the assets available for distribution are insufficient to pay the holders of BPS Series B preferred stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After payment of the full liquidation to the holders of Series B preferred stock, the holders of Series A preferred stock will be entitled to receive $1.75 per share, plus any declared and unpaid dividends out of the assets of BPS available for distribution before any payment of any amount to holders of BPS common stock. If the assets available for distribution are insufficient to pay the holders of Series A preferred stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After payment of the full liquidation to the holders of Series A and B preferred stock, the holders of the Series A common stock will be entitled to receive $0.10 per share ($0 at June 30, 2011 and $700,000 at December 31, 2010 and 2009) out of the assets of BPS available for distribution before any payment of any amount to holders of the Series B common stock. If the assets available for distribution are insufficient to pay the holders of Series A common stock, then such holders will share ratably in any distribution of the assets of BPS in proportion to the amounts that would have been payable with respect to their shares if all amounts payable with respect to such shares were paid in full.

After the payment of the full liquidation preference of the Series A and B preferred stock and Series A common stock, the assets of BPS legally available for distribution, if any, shall be distributed

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ratably to the holders of the Series A common stock and Series A and B preferred stock on an as-if-converted-to-common-stock basis until such time as the holders of Series A preferred stock have received an aggregate amount equal to two times the original issue price ($0 at June 30, 2011 and $5.1 million at December 31, 2010 and 2009) and the holders of Series B preferred stock have received an aggregate amount equal to one and one-half times the original issue price ($0 at June 30, 2011 and $6.1 million at December 31, 2010 and $1.5 million at December 31, 2009). Thereafter, the remaining assets of BPS legally available for distribution, if any, shall be distributed ratably to the holders of the Series A and B common stock.

(d) Registration Rights.

Prior to the acquisition by NewLink of the minority interest in BPS, under an amended and restated investor rights agreement, following an IPO, certain holders of BPS common stock had the right to require BPS to register their shares with the SEC so that those shares could be publicly resold, or to include those shares in any registration statement BPS filed, subject to specified exemptions, conditions and limitations.

13. Common Stock Equity Incentive Plan

In April 2000, the stockholders approved NewLink's 2000 Equity Incentive Plan (the "2000 Plan"), and in July 2009, the stockholders approved NewLink's 2009 Equity Incentive Plan (the "2009 Plan"). Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, NewLink may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, Board of Directors, advisors, and consultants to NewLink. As of June 30, 2011 and December 31, 2010 and 2009, an aggregate of 8,385,000, 6,885,000 and 5,505,500 shares of common stock, respectively, were reserved for issuance under the 2009 Plan. In May 2010, stockholders authorized an increase of 2,600,000 shares of common stock available for issuance under the plan. On January 7, 2011, stockholders authorized an increase of 1,500,000 shares of common stock available for issuance under the 2009 Plan.

On October 29, 2010, the Company adopted an Employee Stock Purchase Plan and a Director Stock Option Plan and reserved 950,000 shares of common stock for issuance under the plans. These plans are inactive until the Company completes a successful IPO.

Stock Options

The fair value of the awards shall be determined by the Board of Directors in good faith until such time as NewLink's common stock is traded on an established exchange at which time the fair value will be the quoted market price as listed on the public exchange. The estimated fair value of the common stock has been determined by management with the assistance of a third-party appraisal report and an

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evaluation of milestones achieved. Under provisions of the 2009 Plan, if Incentive Stock Options (ISO) are granted to a 10% stockholder in NewLink, the exercise price shall not be less than 110% of the common stock's fair market value on the date of grant.

In 2008, all options were granted at an exercise price of $1.00 per share. Additionally, during 2008, NewLink revised the exercise price for 364,000 options under the Plan. The options were previously issued with exercise prices of $1.75, $2.00, or $3.40 per share and were modified to an exercise price of $1.00 per share. The result of this change was an increase in compensation expense of $0 and $34,000 for the years ending December 31, 2010 and 2009, respectively. In January 2009, options were issued at an exercise price of $1.00 per share. In March 2010, options were issued at an exercise price of $1.41 per share for grants dated in December 2009, which were subject to pricing based on finalizing NewLink's valuation as of December 31, 2009. In June 2010, options were issued at an exercise price of $1.46 per share for grants dated in December 2009 and March 2010, which were subject to pricing based on finalizing NewLink's valuation as of March 31, 2010. In October 2010, options were issued at an exercise price of $1.91 per share for grants dated in June 2010, which were subject to pricing based on finalizing NewLink's valuation as of June 30, 2010.

The life of the options is 10 years under the 2009 Plan unless an ISO is granted to a stockholder who owns more than 10% of NewLink's outstanding stock, in which case the life may not exceed five years.

The NewLink Board of Directors determines the vesting period for each stock option award. Generally, stock options awarded to date under the 2009 Plan vest 20% or 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 36 to 48 months, though some options have effective vesting periods that begin prior to the date of grant. In such cases, compensation expense is recognized for the vested portion of the award upon grant. The stock options may include provisions for early exercise of options. If any shares acquired are unvested, they are subject to repurchase at NewLink's discretion until they become vested.

Share-based employee compensation expense for the six months ended June 30, 2011 and the years ended December 31, 2010, 2009, 2008, from inception through December 31, 2010 and since inception was $978,000, $1,525,000, $929,000, $86,000, $2.6 million, and $3.5 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of $0. As of June 30, 2011, the total compensation cost related to nonvested option awards not yet recognized was $3.4 million and the weighted average period over which it is expected to be recognized was 1.6 years. As of December 31, 2010, the total compensation cost related to nonvested option awards not yet recognized was $3.4 million and the weighted average period over which it is expected to be recognized was 1.9 years. As of December 31, 2009, the total compensation cost related to nonvested option awards not yet recognized was $977,000 and the weighted average period over which it is expected to be recognized was 1.8 years.

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The following table summarizes the stock option activity for the six months ended June 30, 2011:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	6,158,822	$ 1.27	
Options granted	388,578	3.54	
Options exercised	25,119	4.75	
Options forfeited	8,314	1.62	
Options expired	—	—	
Outstanding at end of period	6,513,967	$ 1.39	
Options exercisable at end of period	3,984,777	$ 1.31	7.4

On January 7, 2011, all options to purchase BPS common stock were exchanged for 106,078 options to purchase NewLink stock with a weighted average exercise price of $0.62, which are included in options granted above. See note 20.

The following table summarizes stock option activity for the year ended December 31, 2010:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	3,748,500	$ 0.92	
Options granted	2,725,250	1.43	
Options exercised	(259,428)	0.32	
Options forfeited	(55,500)	1.00	
Options expired	—	—	
Outstanding at end of period	6,158,822	$ 1.27	8.2
Options exercisable at end of period	3,135,888	$ 1.18	7.7

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The following table summarizes stock option activity for the year ended December 31, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	1,545,500	$ 0.79	
Options granted	2,267,000	1.00	
Options exercised	(52,865)	0.28	
Options forfeited	(11,135)	1.00	
Options expired	—	—	
Outstanding at end of period	3,748,500	$ 0.92	8.1
Options exercisable at end of period	2,208,241	$ 0.87	7.5

The following table summarizes the stock option activity for the six months ended June 30, 2011 and the assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

Number of options granted	408,578
Risk-free interest rate	2.1%-3.8%
Expected dividend yield	—
Expected volatility	64.5%-67.7%
Expected term (in years)	5.4-7.5
Weighted average grant-date fair value per share	$3.31

The intrinsic value of options exercised during the six months ending June 30, 2011 was $119,000. The fair value of awards vested during the six months ending June 30, 2011 was $4.2 million.

The following table summarizes options that were granted during the years ended December 31, 2010 and 2009, and the assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Year Ended		
	2008	2009	2010
Number of options granted	963,500	2,267,500	2,725,250
Risk-free interest rate	1.5%-3.3%	1.6%	2.3%-3.5%
Expected dividend yield	—	—	—
Expected volatility	54.5%-67.2%	69.4%	59.8%-68.1%
Expected term (in years)	5.5-7.5	7.5	5.0-7.5
Weighted average grant-date fair value per share	$0.49-0.58	$0.49	$1.38

The intrinsic value of options exercised during the year ended December 31, 2010 was $82,000. The fair value of awards vested during the year ended December 31, 2010 was $3.7 million.

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Although NewLink does not have a formal policy regarding the source of shares issued upon exercise of stock options, these shares were generally issued from treasury stock. As all treasury shares were retired in 2007, NewLink expects shares issued upon future stock option exercises to be new shares.

During the six months ended June 30, 2011 and the years ended December 31, 2010, 2009 and 2008, from inception through December 31, 2010, and since inception 271,000, 305,000, 0, 251,000, 651,000 and 922,000 stock options and awards were granted to nonemployees, respectively. As a result of the issuance of these options and awards, $236,000, $147,000, $90,000, $13,000, $408,000 and $644,000 of expense was recorded in the six months ended June 30, 2011 and the years ended 2010, 2009 and 2008, from inception through December 31, 2010, and since inception, respectively.

14. Subsidiary Common Stock Equity Incentive Plan

In September 2006, the BPS stockholders approved BPS's 2006 Equity Incentive Plan (the "BPS Plan"). Under the provisions of the BPS Plan, prior to the merger described in note 20, BPS could have granted the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the BPS Plan, as amended, could have been be made to officers, employees, Board of Directors, advisors, and consultants to BPS. During 2007, BPS authorized up to 3,000,000 shares of BPS's common stock to be awarded under the BPS Plan. During 2008, BPS authorized an increase in the number of shares of BPS's common stock available under the BPS Plan to 3,253,341. During 2009, BPS authorized an increase in the number of shares of BPS's common stock available under the BPS Plan to 3,453,341.

Stock Options

The fair value of the awards was determined by the BPS Board of Directors in good faith. The estimated fair value of the common stock was determined by management based on BPS milestones achieved, which provided additional value and the issuance price of preferred stock, discounted for preference items for the Series A and B Preferred, sold to third-party investors. Under provisions of the BPS Plan, if ISOs were granted to a 10% stockholder in BPS, the exercise price could not be less than 110% of the BPS common stock's fair market value on the date of grant. All stock options granted in 2010 had an exercise price of $0.25 per share. All stock options granted in 2009 had an exercise price of $0.10 per share.

The life of the options is 10 years under the BPS Plan unless an ISO is granted to a stockholder who owns more than 10% of BPS's outstanding stock, in which case the life may not exceed five years.

The BPS Board of Directors determined the vesting period for each stock option award. Generally, stock options awarded to date under the BPS Plan vest 25% on the first anniversary date of issuance with the remaining options vesting ratably over the next 24 to 48 months.

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Share-based employee compensation expense for the years ended December 31, 2010, 2009, 2008, and since inception was $20,000, $19,000, $35,000, and $126,000, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of $0. As of December 31, 2010, the total compensation cost related to nonvested option awards not yet recognized was $17,000 and the weighted average period over which it is expected to be recognized was 1.7 years. As of December 31, 2009, the total compensation cost related to nonvested option awards not yet recognized was $15,000 and the weighted average period over which it is expected to be recognized was 2.4 years.

The following table summarizes stock option activity for the year ended December 31, 2010:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	227,500	$ 0.10	
Options granted	169,000	0.25	
Options exercised	—	—	
Options forfeited	(2,500)	0.10	
Options expired	—	—	
Outstanding at end of period	394,000	$ 0.16	8.4
Options exercisable at end of period	216,033	$ 0.18	8.4

The following table summarizes stock option activity for the year ended December 31, 2009:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	40,000	$ 0.09	
Option granted	189,000	0.10	
Options exercised	—	—	
Options forfeited	(1,500)	0.10	
Options expired	—	—	
Outstanding at end of period	227,500	$ 0.10	8.9
Options exercisable at end of period	56,025	$ 0.09	8.9

The fair value of awards vested during the year ended December 31, 2010 was $247,000. The fair value of awards vested during the year ended December 31, 2009 was $70,446.

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The following table summarizes options that were granted during the years ended December 31, 2010 and 2009 and the assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Year Ended		
	2008	2009	2010
Number of options granted	31,200	189,000	169,000
Risk-free interest rate	1.7%-2.7%	1.6%-2.3%	1.3%-1.9%
Expected dividend yield	—	—	—
Expected volatility	75.2%-75.5%	62.5%-64.2%	61.7%-63.2%
Expected term (in years)	7.0-7.5	7.5	5.5-7.5
Weighted average grant date fair value per share	$0.07	$0.06-0.07	$0.14

BPS common stock bonuses during the years ended December 31, 2010, 2009, 2008, and from inception totaled 0, 0, 1,200, and 58,343 shares, respectively. To date, there have been no issues of rights to acquire restricted common stock.

During the years ended December 31, 2010, 2009, 2008, and since inception, 155,000, 30,000, 0, and 355,000 in stock options were granted to nonemployees, respectively. As a result of the issuance of these options, $2,000, $3,000, $2,000, and $10,000 of expense was recorded in the years ended December 31, 2010, 2009, 2008, and since inception, respectively.

15. Income Taxes

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at June 30, 2011 are presented below (in thousands):

Deferred tax assets:	
Net operating loss carryforwards	$ 13,969
Federal research credits	2,618
Gross deferred tax assets	16,587
Less valuation allowance	(16,409)
Net deferred tax assets	178
Deferred tax liability:	
Equipment	(178)
Total net deferred tax assets	$ —

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The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2010 and 2009 are presented below (in thousands):

	Year Ended	
	2009	2010
Deferred tax assets:		
Net operating loss carryforwards	$ 9,786	$ 13,042
Federal research credits	1,888	2,101
Gross deferred tax assets	11,674	15,143
Less valuation allowance	(11,581)	(15,017)
Net deferred tax assets	93	126
Deferred tax liability:		
Equipment	(93)	(126)
Total net deferred tax assets	$ —	$ —

The valuation allowance for deferred tax assets as of June 30, 2011 and December 31, 2010 and 2009 was $16.4 million, $15.0 million and $11.6 million, respectively. The net change in the total valuation allowance for the six months ended June 30, 2011 and the years ended December 31, 2010 and 2009 was an increase of $1.4 million, $3.4 million and $1.6 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of December 31, 2010 and 2009, due to the uncertainty of future recoverability.

Federal operating loss carryforwards as of December 31, 2010 for approximately $62.1 million and federal research credit carryforwards of approximately $2.1 million expire at various dates from 2020 through 2030. Sections 382 and 383 of the Internal Revenue Code limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2009, NewLink experienced Section 382 ownership changes in September 2001 and March 2003. These two ownership changes limit NewLink's ability to utilize its federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the 2003 ownership change. In addition, the net operating loss carryforwards (and certain other tax attributes) of NewLink's subsidiary may be limited by Sections 382 and 383 as a result of a prior ownership change of the subsidiary.

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Additional analysis will be required to determine whether changes in the Company's ownership since December 31, 2009 and/or changes in the Company's ownership that will result from this offering have caused or will cause another ownership change to occur, and the conclusions will depend on the terms of the IPO and other information that may not be available to us until after the IPO has occurred. Any such change could result in significant limitations on all of the Company's net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred and does not occur as a result of the IPO, additional ownership changes may occur in the future as a result of events over which the Company will have little or no control, including purchases and sales of the Company's equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company's stock or certain changes in the ownership of any of the Company's 5% stockholders.

The Company incurred no income tax expense for the six months ended June 30, 2011 and the years ended December 31, 2010, 2009 and 2008, for the period from inception through December 31, 2010 or since inception. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

16. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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The following table presents the computation of basic and diluted net loss per common share (in thousands, except per share data):

	Years Ended December 31,			Six Months Ended June 30,	
	2008	2009	2010	2010	2011
Historical net loss per share					
Numerator					
Net loss attributable to common stockholders	$ (8,842)	$ (9,974)	$ (16,213)	$ (7,087)	$ (8,291)
Denominator					
Weighted-average common shares outstanding	6,542	6,636	7,040	6,710	7,647
Denominator for basic and diluted net loss per share	6,542	6,636	7,040	6,710	7,647
Basic and diluted net loss per share	$ (1.35)	$ (1.50)	$ (2.30)	$ (1.06)	$ (1.08)
Pro forma net loss per common share (unaudited)					
Numerator					
Net loss attributable to common stockholders			(16,213)		(8,291)
Net loss used to compute pro forma net loss per share			(16,213)		(8,291)
Denominator					
Basic and diluted weighted-average common shares, as used above			7,040		7,647
Weighted-average shares used in computing pro forma basic and diluted net loss per common share					
Pro forma basic and diluted net loss per common share			$		$

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The numerator was not adjusted for the stock dividend paid on the Series AA preferred stock as the impact is not material. Potentially dilutive securities not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common equivalent shares):

	As of December 31,			Six Months Ended June 30,	
	2008	2009	2010	2010	2011
Preferred stock(1)	9,870,390	13,783,769	14,994,048	13,783,769	17,157,438
Common stock warrants	—	375,000	—	375,000	—
Common stock options	1,545,500	3,748,500	6,158,822	6,385,303	6,513,967
	11,415,890	17,907,269	21,152,870	20,544,072	23,671,405

(1) 2010 and 2011 amounts are estimated for the current Series E conversion, assuming a conversion price of $6.25 per share.

As discussed in note 10, the Series Preferred will automatically convert into common stock immediately upon the closing of an IPO of common stock pursuant to an effective registration statement filed by the Company under the Securities Act of 1933 that generates aggregate gross proceeds of not less than $20.0 million. In the event of such a conversion, and assuming such shares were outstanding for the entire year and that the price per share at which common stock is sold to the public in the offering is $6.25, which is the current Series E conversion price, the Company would have weighted-average common shares outstanding of 24,804,669 for the six months ended June 30, 2011 and 24,197,333 for the year ended December 31, 2010, resulting in a basic and diluted net loss per share of $0.33 and $0.67, respectively.

17. Licensing Agreements

The Company is subject to a number of licensing agreements with respect to certain of the technologies that underlie its intellectual property. Unless otherwise noted, these agreements typically provide that the Company has exclusive rights to the use and sublicensing of the technologies in question for the duration of the intellectual property patent protection in question, subject to the Company meeting its financial and other contractual obligations under the agreements. The Company expenses all payments made under the following agreements in the period the payments occurred. For additional information regarding how the Company records payments under these agreements, see note 2(k) above. Certain of the key licensing agreements include the following:

Central Iowa Health Systems. The Company is a party to a license agreement, or the CIHS Agreement, dated August 2, 2001, with the Central Iowa Health System, or CIHS. The CIHS Agreement grants the Company an exclusive, worldwide license to make, have made, use, import, sell and offer for sale products that are covered by certain CIHS patent rights, proprietary information and know-how relating to the Company's HyperAcute immunotherapy technology. In partial consideration of the license under the CIHS Agreement, the Company entered into a stock purchase agreement with CIHS, under which the Company issued to CIHS shares of its common stock and granted CIHS certain rights related to ownership of such shares.

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In addition, the Company must reimburse CIHS for out-of-pocket costs incurred for patent prosecution and maintenance. If the Company commercializes a licensed product, it also has the obligation to pay CIHS royalties as a low single-digit percentage of net sales of the licensed product, subject to annual minimum royalties and a reduction for any royalty payments the Company must make to third parties. If the Company grants a sublicense under the licenses granted by CIHS, it must pay to CIHS a percentage of certain consideration paid by the sublicensee to the Company. Under the CIHS Agreement, the Company must use commercially reasonable efforts to develop and commercialize licensed products, to obtain necessary regulatory approvals and to launch and market such products in specified markets.

Unless terminated earlier, the CIHS Agreement shall remain in effect until the expiration of all of the Company's royalty obligations under the agreement. The Company may terminate the agreement, or specific patents covered by the agreement, on written notice to CIHS or for CIHS' uncured material breach of the agreement. CIHS has the right to terminate for the Company's uncured material breach of the agreement after written notice. Upon termination of the agreement the Company may sell its existing inventory of licensed products for a period of three months after such termination.

Drexel University. The Company is party to a license agreement, or the Drexel Agreement, dated October 13, 2004 with Drexel University, or Drexel. The Drexel Agreement grants the Company, and its affiliates, an exclusive, worldwide license, under specified Drexel patent rights relating to compositions and methods for vaccines based on alpha-galactosyl epitopes, to make, have made, use, import, sell and offer for sale vaccine products that are covered by such patent rights, or that use related Drexel technical information, for use in the diagnosis and treatment of cancer, viral and other infectious disease.

In consideration of the Company's license under the Drexel Agreement, it has paid and is obligated to continue to pay specified license fees, potential milestone payments in an aggregate amount up to approximately $1 million for each licensed product, annual license maintenance fees, reimbursement of patent prosecution costs, and royalty payments as a low single-digit percentage of "net sales" of any licensed product that is commercialized, subject to minimum royalty payments. Royalty rates vary depending on the type of licensed product, the territory where it is sold and whether the licensed product is combined with other technologies. In addition, if the Company grants a sublicense under the license granted by Drexel, it must pay Drexel a percentage of the consideration paid by the sublicensee to the Company. In accordance with a development plan included in the Drexel Agreement, the Company is obligated to use commercially reasonable efforts to develop and market products covered by the license as soon as practicable.

Unless terminated earlier, the Drexel Agreement shall remain in effect until the expiration or abandonment of all the licensed Drexel patents. The Company may terminate the Drexel Agreement on written notice to Drexel. Drexel has the right to terminate for the uncured breach of the Company's obligations under the agreement or for certain other reasons. If the Drexel Agreement terminates the Company may, in certain circumstances, sell any remaining inventory of licensed products for a period of six months after termination.

Lankenau Institute for Medical Research—IDO-1. The Company is a party to a license agreement dated July 7, 2005, as amended May 22, 2006 and September 11, 2007, or the IDO-1 Agreement, with Lankenau Institute for Medical Research, or LIMR. The IDO-1 Agreement grants the Company an

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exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of indoleamine 2,3-dioxygenase, or IDO-1, and related LIMR technology, to make, have made, use, import, sell and offer for sale products that are covered by such patent rights for use in the field of animal and human therapeutics and diagnostics.

In consideration of the license grant, the Company is obligated to pay to LIMR specified license fees, annual license maintenance fees, reimbursement of past patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.36 million for each licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized. In addition, if the Company grants a sublicense under the IDO-1 Agreement, it must to pay to LIMR a percentage of the consideration received by the Company from the sublicensee. Under the IDO-1 Agreement, the Company is obligated to use commercially reasonable efforts to develop and market the licensed products, and to achieve certain milestones by agreed-upon deadlines.

Unless terminated earlier, the IDO-1 Agreement shall remain in effect until the expiration of the last licensed LIMR patents. LIMR may terminate the agreement for the Company's failure to achieve specified milestones, failure to make payments due, bankruptcy or similar proceedings. Upon termination of the agreement, the Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

Medical College of Georgia. The Company is a party to a License Agreement dated September 13, 2005, or the MCGRI Agreement, with Medical College of Georgia Research Institute, or MCGRI, which was amended on April 27, 2006 and February 13, 2007. The MCGRI Agreement grants the Company, including its affiliates, an exclusive, worldwide license, under specified MCGRI patent rights and related technology to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology in all medical applications.

In consideration of such license grant, the Company is obligated to pay to MCGRI specified license fees (including issuing shares of its common stock), annual license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $2.8 million per licensed product, and royalties as a single-digit percentage of net sales of the licensed products, subject to minimum royalty payments and royalty rates depending on the type of license product. In addition, if the Company grants a sublicense under the license granted by MCGRI, it must pay to MCGRI a percentage of the consideration it receives from the sublicensee. Under the agreement, the Company is obligated to make certain investments toward the further development of licensed products within specified time periods.

Unless terminated earlier, the MCGRI Agreement will remain in effect until the expiration of the last licensed MCGRI patents. MCGRI may terminate this agreement for the Company's uncured material breach, bankruptcy or similar proceedings. The Company may terminate this agreement for the uncured material breach of MCGRI. For a period of one year following the termination of the agreement, the Company may sell its licensed products that are fully manufactured and part of its normal inventory at the date of termination.

University of British Columbia. The Company is a party to a license agreement dated February 1, 2007, or the UBC License, with the University of British Columbia, or UBC. The UBC License grants the

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Company an exclusive, worldwide license, under specified UBC patent rights relating to IDO-1 inhibitors and related technology, to make, have made, use, import, sell and offer for sale products that are covered by licensed patent rights or incorporates or uses licensed technology. In addition, the UBC License grants the Company an option to obtain an exclusive, worldwide license to new IDO-1 inhibitors related technology developed during the term of the agreement.

In consideration of the license grant, the Company must pay to UBC specified license fees, annual payment and license maintenance fees, reimbursement of patent prosecution costs, potential milestone payments in an aggregate amount up to approximately $1.8 million per licensed product, and royalties in a range of 10% or less of net revenue of the licensed product if a licensed product is commercialized, which royalty rate varies depending on the type of license product and field of use. In addition, if the Company grants a sublicense under the licenses granted by UBC, it may be required to pay to UBC a percentage of certain consideration it receives from the sublicensee. The Company is obligated to use its commercially reasonable efforts to develop and market the licensed products, and to achieve certain specific development milestones by agreed-upon deadlines.

Unless terminated earlier, the UBC License will remain in effect for 20 years or until the expiration of the last licensed UBC patents, whichever is later. UBC may terminate this agreement for the Company's uncured material breach, bankruptcy or similar proceedings. The Company may terminate this agreement for the uncured material breach of UBC. Upon termination of the agreement, the Company may not sell any inventory of the licensed product without the prior written consent of UBC.

LIMR—IDO-2. The Company is a party to a license agreement, or the LIMR IDO-2 Agreement, executed December 21, 2007 with LIMR. The LIMR IDO-2 Agreement grants the Company an exclusive, worldwide license, under specified LIMR patent rights relating to inhibitors of the target Indoleamine 2,3 Dioxygenase-2, or IDO-2, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses.

In consideration of the license grant, the Company has paid to LIMR an upfront license fee and annual license maintenance fees, and is obligated to pay LIMR annual license maintenance fees, potential milestone payments in an aggregate amount up to approximately $1.52 million per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement, and, if a licensed product is commercialized, royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for the Company's royalty payments to third parties. In addition, if the Company grants a sublicense under the licenses granted by LIMR, it must pay to LIMR a percentage of the consideration paid by the sublicensee to the Company. Under the LIMR IDO-2 Agreement, the Company has agreed to use its commercially reasonable efforts to develop and exploit products covered by the license.

Unless terminated earlier, the LIMR IDO-2 Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. The Company may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for the Company's uncured material breach, failure to pay, or bankruptcy or similar proceedings. Upon termination of the agreement, The Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

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2009 LIMR Exclusive License Agreement. The Company is a party to a license agreement, or the 2009 LIMR Agreement, dated April 23, 2009 with LIMR. The 2009 LIMR Agreement grants the Company an exclusive, worldwide license, under specified LIMR patent rights relating to IDO inhibitors, and under related LIMR know-how or technology, to make, have made, use, import, sell and offer for sale products and services that are covered by such patent rights, for all uses. In consideration of such license grant, the Company is obligated to pay LIMR potential milestone payments in an aggregate amount up to approximately $610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement, and royalties as a low single-digit percentage of "net sales" of the licensed product, subject to reduction for the Company's royalty payments to third parties and to LIMR under the IDO-1 Agreement or LIMR IDO-2 Agreement. In addition, if the Company grants a sublicense under the licenses granted by LIMR, it must pay to LIMR a percentage of the consideration paid by the sublicensee to us.

Unless terminated earlier, the LIMR IDO Agreement shall continue until the expiration of the last valid LIMR patent licensed under the agreement. The Company may terminate the Agreement on written notice to LIMR. LIMR has the right to terminate for the Company's uncured material breach, failure to pay, or bankruptcy or similar proceedings. Upon termination of the agreement, the Company may sell its current inventory of licensed products and those licensed products in the process of manufacture, subject to the terms of the agreement.

Bresagen Patent License Agreement. The Company is a party to a license agreement, or the Bresagen Agreement, dated March 1, 2006 with Bresagen Xenograft Marketing Ltd, or Bresagen. The Bresagen Agreement grants the Company a non-exclusive, non-sublicensable license to specified Bresagen patent rights for use in testing microbial and cancer vaccines. In consideration of such license grant, the Company is obligated to pay Bresagen an up front license fee and an annual license fee.

Unless terminated earlier, the Bresagen Agreement shall continue for an initial period of eight years, which may be extended an additional five years upon agreement of the parties. Either party may terminate the Agreement at any time by agreement in writing, each party not to unreasonably withhold its consent for termination. Bresagen has the right to terminate for the Company's uncured breach, insolvency, change of control without consent or similar proceedings. Upon termination of the agreement, all of the Company's rights under the license are terminated.

During 2010, the Company issued 50,000 shares to Reconstitute, LLC as consideration for terminating a licensing agreement and for performance of certain provisions of the license agreement prior to termination. The fair value of the shares issued was approximately $201,000.

18. Employee Benefit Plans

The Company sponsors a 401(k) plan, which includes a defined contribution feature. The Company contributed $89,000, $137,000, $90,000, $120,000, $508,000 and $597,000 for the six months ended June 30, 2011 and the years ended December 31, 2010, 2009, 2008, from inception to December 31, 2010 and since inception, respectively.

On October 29, 2010, the Company approved employment agreements for certain executives that provide for the payment of 24, 12 or 6 months of base salary upon termination of the executive in certain

NewLink Genetics Corporation and Subsidiary
(A Development Stage Enterprise)

Notes to Consolidated Financial Statements (Continued)

(Information as of June 30, 2011, for the six-month periods ended June 30, 2011 and 2010, and for the cumulative period June 4, 1999 (inception) through June 30, 2011 is unaudited)

circumstances and group health insurance premiums plus accrued obligations. The agreements include provisions to accelerate the vesting of stock options subject to certain events including those related to a change in control.

19. Related-Party Transactions

As of December 31, 2009, the Company was owed $850,000 in various notes receivable and $25,000 in notes receivable for common stock by its executive management team. The notes carried interest rates ranging from 2.42% to 6.00% and matured within the next 16 months. On May 7, 2010, the Board of Directors voted to forgive notes receivable and related outstanding interest from two officers. The remaining balances were repaid. Bonuses of $192,236 were paid to cover the resulting tax liabilities for these individuals. To offset the forgiveness, outstanding options held by the officers to purchase common stock were modified to increase the aggregate exercise price by $592,406 on July 1, 2010.

Certain purchasing activities are outsourced to a company owned by an immediate family member of the Company's controller. Total purchases through this related party were $1,000, $40,000, $30,000, $78,000, $270,000, and $271,000 for the six months ended June 30, 2011 and the years ended December 31, 2010, 2009, 2008, from inception through December 31, 2010 and since inception through June 30, 2011, respectively. The Company paid fees to this related party for consulting services of approximately $0, $0, $0, $0, $7,000 and $7,000 for the six months ended June 30, 2011 and the years ended December 31, 2010, 2009, 2008, from inception through December 31, 2010 and since inception, respectively.

20. Acquisition of BioProtection Systems Corporation

On January 7, 2011, NewLink acquired all of the minority interest in BPS, by merging a newly-formed subsidiary of NewLink's with BPS, with BPS as the surviving corporation. In connection with this transaction, NewLink agreed to issue up to an aggregate of 276,304 shares of NewLink's Series E preferred stock with a value of $8.6 million to the former holders of BPS Series B common stock, Series A preferred stock and Series B preferred stock (other than NewLink). 221,066 of the shares of NewLink's Series E preferred stock were issued to the holders of the BPS Series B common stock, Series A preferred stock and Series B preferred stock upon the closing of the merger. The remaining 55,238 shares of NewLink's Series E preferred stock were held back to satisfy any indemnity obligations under the merger agreement. There were no indemnity obligations owed to BPS and these remaining shares were issued on August 12, 2011 to the former stockholders of BPS (unaudited). As a result of this transaction, BPS became a wholly-owned subsidiary of NewLink. All options to purchase shares of BPS common stock became options to purchase NewLink's common stock. As part of the merger agreement, each outstanding BPS option was converted into the right to receive the number of NewLink options equal to the product of (A) the number of shares of BPS common stock subject to such BPS option multiplied by (B) a fraction, the numerator of which is $1.0825 and the denominator of which is $4.02, which was the fair market value of one share of NewLink common stock on September 30, 2010. As part of the merger agreement each outstanding BPS option was converted into the right to receive that number of NewLink options equal to the product of (A) the number of shares of BPS common stock subject to such BPS option multiplied by (B) a fraction, the numerator of which is $1.0825 and the denominator of which is $4.02, which was the fair market value of one share of NewLink common stock as of September 30, 2010. The exchange of options will be accounted for as a modification of an equity-classified award. The Series E preferred stock was issued with

NewLink Genetics Corporation and Subsidiary
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Notes to Consolidated Financial Statements (Continued)

(Information as of June 30, 2011, for the six-month periods ended June 30, 2011 and 2010, and for the cumulative period June 4, 1999 (inception) through June 30, 2011 is unaudited)

similar price and terms as the shares sold to third-parties in December 2010. See note 10 and note 11. As NewLink and BPS are under common control, the acquisition is treated as an equity transaction. The net assets of BPS had a book value of $2.9 million. The remaining amount paid of $5.7 million was recorded as a reduction of additional paid-in capital. No gain or loss was recorded as a result of this transaction.

21. Subsequent Events (Unaudited)

On December 13, 2010, the Company's Board of Directors approved an amendment to the Company's certificate of incorporation that we plan to file shortly prior to consummating this offering. Among other things, the amendment will eliminate the requirement that the per share price to the public in this offering be at least $7.00 in order to result in the conversion of the outstanding preferred stock of the Company into common stock in connection with this offering. This amendment was subsequently approved by the Company's stockholders on January 7, 2011.

In July 2011, the Company's nonemployee director compensation policy was amended to change the vesting period for the initial grant of stock options from five years to three years. All outstanding director grants shall be amended accordingly.

On July 29, 2011, the Company's Board of Directors approved an amendment to the Company's Restated Certificate of Incorporation extending the date by which this offering must close in order to result in the adjustment to the conversion price of the Series E preferred stock discussed in note 2(j) above. This amendment was subsequently approved by the Company's stockholders on September 10, 2011.

Shares

Common Stock

PRELIMINARY PROSPECTUS

, 2011

Stifel Nicolaus Weisel

Canaccord Genuity

Baird

Until , 2011, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to unsold allotments or subscriptions.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other expenses of issuance and distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the listing fee for the NASDAQ Global Market.

	Amount Paid or to be Paid
SEC registration fee	$ 6,150
FINRA filing fee	9,125
The NASDAQ Global Market listing fee	25,000
Blue sky qualification fees and expenses	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* to be provided by amendment

Item 14. Indemnification of directors and officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws, each of which will

become effective upon the completion of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the Board of Directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of NewLink or any of its affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

We have entered into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

Exhibit Document	Number
Form of Underwriting Agreement	1.1
Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering	3.2
Form of Amended and Restated Bylaws to be effective upon completion of this offering	3.4
Form of Indemnity Agreement	10.50

Item 15. Recent sales of unregistered securities.

The following list sets forth information regarding all securities sold by us in the three years preceding the filing of this Registration Statement:

(1) Between February 8, 2008 and December 17, 2009, in connection with our Series C preferred stock financing, we issued and sold an aggregate of 6,000,000 shares of Series C preferred stock to 142 accredited investors at 33 closings, at a purchase price of $5.00 per share, for aggregate consideration of $30.0 million. Upon completion of this offering, these shares will convert into 6,000,000 shares of common stock.

(2) On July 17, 2009, in connection with our Series D preferred stock financing, we issued and sold an aggregate of 1,500,000 shares of Series D preferred stock to one accredited investor at one closing, at a purchase price of $5.00 per share, for aggregate consideration of $7.5 million. Upon completion of this offering, these shares will convert into 1,500,000 shares of common stock.

(3) Between December 1, 2010 and December 13, 2010, in connection with our Series E preferred stock financing, we issued and sold an aggregate of 248,320 shares of Series E preferred stock to 39 accredited investors at two closings, at a purchase price of $31.25 per share, for aggregate consideration of $7.8 million. Upon completion of this offering, these shares will convert into 1,241,600 shares of common stock.

(4) On July 17, 2009, we issued a warrant to Midwest Oilseeds, Inc. to purchase an aggregate of 375,000 shares of our common stock, with an initial exercise price of $7.20 per share. On October 7, 2010, this warrant was amended and on October 21, 2010 the warrant was exercised for 375,000 shares of common stock at an aggregate exercise price of $2.0 million.

(5) From October 30, 2000 to August 6, 2008, we granted stock options under our 2000 Equity Incentive Plan to purchase 1,697,152 shares of common stock (net of expirations and cancellations) to our employees, directors and consultants, having exercise prices ranging from $0.25 to $3.40 per share. Of these, options to purchase 475,080 shares of common stock have been exercised through December 31, 2010, for aggregate consideration of $141,543, at exercise prices ranging from $0.25 to $1.75 per share. In addition, we granted stock awards for 38,787 shares of our common stock in exchange for services rendered.

(6) From May 13, 2009 to December 9, 2010, we granted stock options under our 2009 Equity Incentive Plan to purchase 5,203,250 shares of common stock (net of expirations and cancellations) to our employees, directors and consultants, having exercise prices ranging from $1.00 to $3.41 per share. Of these, none of the options to purchase shares of common stock have been exercised through December 31, 2010.

(7) From May 13, 2009 to December 4, 2009, we granted stock options under our 2009 Equity Incentive Plan to purchase 2,438,275 shares of common stock (net of expirations and cancellations) to Dr. Charles Link, having exercise prices ranging from $1.00 to $2.00 per share.

Of these, none of the options to purchase shares of common stock have been exercised through December 31, 2010.

(8) On September 3, 2010, we issued 50,000 shares of our common stock to Reconstitute, LLC, pursuant to the terms of a Termination Agreement by which we terminated a license agreement with Reconstitute. The stock was issued in consideration of Reconstitute's performance of certain provisions of the license agreement prior to termination and Reconstitute's agreement to terminate the license agreement.

(9) On July 29, 2010, we issued 364,285 shares of our common stock to nine accredited investors pursuant to the July 21, 2005 purchase agreement with the shareholders of OncoRx Corporation. This issuance was the third and final installment of shares payable under the July 21, 2005 purchase agreement.

(10) On January 7, 2011, and August 12, 2011, we issued 276,304 shares of our Series E preferred in connection with the acquisition of BioProtection Systems Corporation.

(11) On June 20, 2011, we issued and sold to an investor an additional 160,000 shares of Series E preferred stock at a purchase price of $31.25 per share, which resulted in gross proceeds of $5.0 million.

The offers, sales and issuances of the securities described in paragraphs (1), (2), (3), (4), (7), (8), (9) and (10) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

The offers, sales and issuances of the securities described in paragraphs (5) and (6) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2000 Equity Incentive Plan or 2009 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

Item 16. Exhibits and Financial Statement Schedules

EXHIBIT INDEX

Exhibit Number	Description
1.1#	Form of Underwriting Agreement
3.1(1)	Restated Certificate of Incorporation filed on November 23, 2010
3.2#	Form of Amended and Restated Certificate of Incorporation to be effective upon completion of this offering
3.3(1)	Bylaws, as currently in effect
3.4#	Form of Amended and Restated Bylaws to be effective upon completion of this offering
3.5	Certificate of Amendment to Restated Certificate of Incorporation filed on September 15, 2011
4.1#	Form of the Registrant's Common Stock Certificate
4.2(1)	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4

Exhibit Number	Description
5.1#	Opinion of Cooley LLP
10.1#	Form of Lock-up Agreement
10.2†(1)	2000 Equity Incentive Plan
10.3†(1)	Form of Stock Option Agreement under 2000 Equity Incentive Plan
10.4†(1)	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan
10.5†(1)	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan
10.6†(1)	Amended and Restated 2009 Equity Incentive Plan
10.7†(1)	Form of Stock Option Agreement under 2009 Equity Incentive Plan
10.8†(1)	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan
10.9†(1)	2010 Employee Stock Purchase Plan
10.10†(1)	2010 Non-Employee Directors' Stock Award Plan
10.11†#	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers
10.12†(1)	Employment Agreement, dated as of December 6, 2010, by and between the Registrant and Charles J. Link, Jr.
10.13†(1)	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Nicholas N. Vahanian
10.14†(1)	Employment Agreement, dated as of June 26, 2008, by and between the Registrant and Gordon H. Link, Jr.
10.15†(1)	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Gordon H. Link, Jr.
10.16†(1)	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Kenneth Lynn
10.17†(1)	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and W. Jay Ramsey
10.18†(1)	Form of Employee Proprietary Information and Inventions Agreement
10.19†(2)	Promissory Note dated May 2, 2008 by and between the Registrant and Charles Link
10.20†(2)	Promissory Note dated April 18, 2000 by and between the Registrant and Nicholas Vahanian
10.21†(2)	Promissory Note dated August 20, 2008 by and between the Registrant and Nicholas Vahanian
10.22†(2)	Promissory Note dated July 2008 by and between the Registrant and Gordon Link
10.23†(2)	Amendment Agreement dated July 1, 2010 by and between the Registrant and Charles Link
10.24†(2)	Amendment Agreement dated July 1, 2010 by and between the Registrant and Nicholas Vahanian
10.25†(2)	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Charles Link
10.26†(2)	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Nicholas Vahanian
10.27†(2)	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Gordon Link
10.28†(2)	Acknowledgment Agreement dated November 24, 2010 by and between BioProtection Systems Corporation and Charles Link
10.29†(2)	Acknowledgment Agreement dated November 23, 2010 by and between BioProtection Systems Corporation and Nicholas Vahanian
10.30*	License Agreement dated July 7, 2005 by and between the Registrant and Lankenau Institute for Medical Research
10.31*(1)	First Amendment to License Agreement dated May 22, 2006 by and between the Registrant and Lankenau Institute for Medical Research

Exhibit Number	Description
10.32*(1)	Second Amendment to License Agreement September 11, 2007 by and between the Registrant and Lankenau Institute for Medical Research
10.33*	Exclusive License Agreement executed December 21, 2007 by and between the Registrant and Lankenau Institute for Medical Research
10.34*	Exclusive License Agreement effective April 23, 2009 by and between the Registrant and Lankenau Institute for Medical Research
10.35*	License Agreement dated February 27, 2007 by and between the Registrant and University of British Columbia
10.36*	License Agreement dated October 13, 2004 by and between the Registrant and Drexel University
10.37*	License Agreement dated August 2, 2001 by and between the Registrant and Central Iowa Health System
10.38*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between the Registrant and National Cancer Institute
10.39	Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between the Registrant and National Cancer Institute
10.40	Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between the Registrant and National Cancer Institute
10.41	Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between the Registrant and National Cancer Institute
10.42	Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between the Registrant and National Cancer Institute
10.43	Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between the Registrant and National Cancer Institute
10.44	Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between the Registrant and National Cancer Institute
10.45	Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute
10.46*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.
10.47*	First Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.
10.48*	Second Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.
10.49*	Third Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.
10.50*(1)	Patent License Agreement dated March 1, 2006 by and between the Registrant and Bresagen Xenograft Marketing Ltd.
10.51(1)	Lease dated September 1, 2000 by and between the Registrant and Iowa State University Research Park Corporation
10.52(1)	Sublease Agreement effective February 1, 2001 by and between the Registrant and Iowa State Innovation System
10.53(1)	Memorandum of Agreement dated December 6, 2005 by and between the Registrant and Iowa State University Research Park Corporation
10.54(1)	Memorandum of Agreement dated April 13, 2006 by and between the Registrant and Iowa State University Research Park Corporation
10.55(1)	Memorandum of Agreement dated February 20, 2008 by and between the Registrant and Iowa State University Research Park Corporation
10.56(1)	Memorandum of Agreement dated May 1, 2009 by and between the Registrant and Iowa State University Research Park Corporation

Exhibit Number	Description
10.57(1)	Memorandum of Agreement dated March 24, 2010 by and between the Registrant and Iowa State University Research Park Corporation
10.58(1)	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation
10.59(1)	Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation
10.60(1)	Forgivable Loan Agreement dated March 10, 2010 by and between the Registrant and City of Ames, Iowa
10.61(1)	Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development
10.62(1)	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development
10.63(1)	Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development
10.64(1)	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development
10.65(1)	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development
10.66*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation
10.67*	Sole License Agreement executed May 4, 2010 by and between Her Majesty the Queen in Right of Canada and BioProtection Systems Corporation
10.68(2)	Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense
10.69(2)	Amendment to Contract No. W911NF-08-C-0044 dated February 12, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.70*	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.71(2)	Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense
10.72(2)	Amendment to Contract No. W911NF-09-C-0072 dated April 21, 2010 by and between BioProtection Systems Corporation and the United States Department of Defense
10.73(2)	Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health
10.74(2)	Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health
10.75(2)	Agreement and Plan of Merger dated December 1, 2010 by and between the Registrant, BPS Merger Sub, Inc., BioProtection Systems Corporation and BPS Stockholder Representative, LLC
10.76(2)	Certificate of Merger of BPS Merger Sub, Inc. into BioProtection Systems Corporation filed on January 7, 2011
10.77(3)	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development
10.78(3)	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development
10.79	Amendment No. 8 to Letter of Intent for CRADA #2166 dated June 2, 2011 by and between the Registrant and National Cancer Institute

Exhibit Number	Description
10.80	Amendment of Contract No. HDTRA1-09-C-0014 dated September 20, 2011 by and between BioProtection Systems Corporation and the United States Department of Defense
10.81	Grant Number 5R43AI084350-02 issued March 24, 2011 by and between BioProtection Systems Corporation and the National Institutes of Health
21.1(1)	Subsidiary Information
23.1	Consent of KPMG LLP, independent registered public accounting firm
23.2(2)	Consent of the Mentor Group, Inc., valuation specialist
23.3#	Consent of Cooley LLP (included in Exhibit 5.1)
24.1(1)	Power of Attorney
24.2(3)	Power of Attorney

(1) Filed with the Registrant's Registration Statement on Form S-1 on December 21, 2010

(2) Filed with the Registrant's Amendment No. 1 to the Registration Statement on Form S-1 on February 28, 2011

(3) Filed with the Registrant's Amendment No. 3 to the Registration Statement on Form S-1 on September 14, 2011

To be filed by amendment

† Indicates management contract or compensatory plan

* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

(b) Financial statement schedule.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 4 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ames, State of Iowa, on October 4, 2011.

NEWLINK GENETICS CORPORATION

By: /s/ CHARLES J. LINK, JR.

Charles J. Link, Jr.
Chief Executive Officer, Chairman of the Board

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 4 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHARLES J. LINK, JR. Charles J. Link, Jr.	Chief Executive Officer, Chairman of the Board and Director *(Principal Executive Officer)*	October 4, 2011
/s/ GORDON H. LINK, JR. Gordon H. Link, Jr.	Chief Financial Officer and Secretary *(Principal Financial and Accounting Officer)*	October 4, 2011
* Thomas A. Raffin	Director	October 4, 2011
* Ernest J. Talarico, III	Director	October 4, 2011
* David J. Lundquist	Director	October 4, 2011
* Sarah Alexander	Director	October 4, 2011
* Joseph Saluri	Director	October 4, 2011
* Paul R. Edick	Director	October 4, 2011

*By: /s/ GORDON H. LINK, JR.

Gordon H. Link, Jr.,
Attorney-in-Fact

Delaware
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "NEWLINK GENETICS CORPORATION", FILED IN THIS OFFICE ON THE FIFTEENTH DAY OF SEPTEMBER, A.D. 2011, AT 7:42 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

3051879 8100

111011717

/s/ Jeffrey W. Bullock
Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 9035019

DATE: 09-16-11

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 08:08 PM 09/15/2011
FILED 07:42 PM 09/15/2011
SRV 111011717 - 3051879 FILE

CERTIFICATE OF AMENDMENT TO THE RESTATED CERTIFICATE OF INCORPORATION OF NEWLINK GENETICS CORPORATION

Charles J. Link, Jr. hereby certifies that:

ONE: The date of filing the original Certificate of Incorporation of this company with the Secretary of State of the State of Delaware was June 4, 1999.

TWO: He is the duly elected and acting Chief Executive Officer of NewLink Genetics Corporation, a Delaware corporation.

THREE: The Board of Directors of the Company, acting in accordance with the provisions of Sections 141 and 242 of the General Corporation Law of the State of Delaware (the "***DGCL***"), adopted resolutions amending its Restated Certificate of Incorporation as follows:

Article IV, second Section L.4(c)(vii) is amended and restated to read as follows:

"**(viii)** The Conversion Price for the Series E Stock shall initially be Six Dollars and Twenty-Five Cents ($6.25) (the "Series E Conversion Price"). Such Series E Conversion Price will be adjusted from time to time in accordance with this Section 4. All references to Series E Conversion Price herein shall mean the Series E Conversion Price as so adjusted. If the Company closes a Qualified Public Offering (as defined below) on or before December 31, 2011, the Conversion Price of the Series E Stock will automatically be adjusted immediately prior to, but contingent upon, the closing of the Qualified Public Offering to a price that is equal to the product of (A) the price at which shares of the Company's Common Stock are sold to the public in such Qualified Public Offering and (B) 0.85 (as adjusted appropriately to reflect any adjustments to the Series E Conversion Price occurring prior to any such adjustment occurring in connection with a Qualified Public Offering)."

FOUR: Thereafter, pursuant to a resolution by the Board of Directors, this Certificate of Amendment was submitted to the stockholders of the Corporation for their approval in accordance with the provisions of Sections 228 and 242 of the DGCL. Accordingly, said proposed amendment has been adopted in accordance with Sections 228 and 242 of the DGCL.

[INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, NewLink Genetics Corporation, Inc. has caused this **CERTIFICATE OF AMENDMENT TO THE RESTATED CERTIFICATE OF INCORPORATION** to be signed by its Chief Executive Officer this 15th day of September, 2011.

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.

Charles J. Link, Jr.
Chief Executive Officer

Exhibit 10.30

LICENSE AGREEMENT BETTWEEN LANKENAU INSTITUTE FOR MEDICAL RESEARCH AND NEWLINK GENETICS CORPORATION

This License Agreement between Lankenau Institute for Medical Research ("LIMR" or "Institute") and NewLink Genetics Corporation. ("NewLink" or "Company") (referred to as "Agreement") for the licensing of certain intellectual property rights to NewLink is made on this 7th day of July, 2005 ("Effective Date").

WHEREAS, LIMR owns certain property rights developed by its employee-investigator, George Prendergast, PhD, and

WHEREAS, NewLink would like to license from LIMR certain technology developed by Dr. Prendergast for the purpose of developing the technology into a marketable therapeutic or diagnostic product.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Definitions.

a. Affiliate(s): Affiliate means any individual, company or entity, in whatever country organized, directly or indirectly, controlling, controlled by, or under common control with NewLink. For purposes of this Agreement, "control" shall mean, direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock or equity of, or more than fifty percent (50%) interest in the income of, such individual, company or entity.

b. Company: Company shall mean NewLink and its Affiliates as defined above.

c. Consideration. "Consideration" shall mean any and all revenues or payments in-kind received by NewLink from a third party as consideration for the grant of a sublicense under the rights granted to NewLink by LIMR pursuant to Article 2, excluding sums received: (i) for the purchase of an equity interest in NewLink at fair market

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value; (ii) as payments or reimbursements for research and development work performed by or on behalf of NewLink; (iii) for purchase of a supply of Licensed Product; (iv) for repayment of any loans, credit or credit line extended by NewLink to such sublicensee; or (v) in the form of a loan, as credit or pursuant to a credit line to NewLink. Notwithstanding the foregoing, if NewLink receives revenue in consideration for the grant of a sublicense under the licenses granted to NewLink hereunder and such sublicense also includes the grant of a license or sublicense to other technology controlled by NewLink but not acquired from LIMR, then the foregoing amount shall be adjusted by a percentage that fairly represents, as reasonably determined by the parties, the contribution of the LIMR Technology and the Patent Rights to the total revenue received by NewLink.

d. Licensed Product: Licensed Product shall mean any article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered by a Valid Claim within the Patent Rights. Licensed Product shall not include other products used in combination with Licensed Product that do not constitute an article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered by a Valid Claim within the Patent Rights.

e. LIMR Technology. "LIMR Technology" shall mean the technology described in **[*]**.

f. Net Sales. "Net Sales" shall mean the gross consideration actually collected by COMPANY and/or any Affiliate from transfer of any Licensed Product to a third party customer, less:

1. revenue credited or rebated on returns and allowances, and bad debts;

2. discounts, in amounts customary in the trade and to the extent actually granted, for quantity purchases, for prompt payments and for wholesalers and distributors;

3. transportation and delivery charges or allowances;

4. customs, duties; and

5. sales, use, excise, value-added and other taxes or other governmental charges measured by sales.

g. Patent Rights: Patent Rights shall mean any and all rights and interest held, acquired or otherwise controlled by LIMR in and to any issued patents and patent applications, including provisional patent applications, any divisions, continuations and continuations

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-in-part thereof, and any foreign counterparts worldwide of such patents or patent applications, that directly arise from the prosecution of **[*]**.

h. Valid Claim: A Valid Claim means a claim of a patent under Patent Rights that (i) has not expired or been abandoned; (ii) has not been disclaimed; (iii) has not been canceled or superseded, or if cancelled or superseded, has not been reasserted; (iv) has not been revoked, held invalid or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such claim in such country from which no further appeal has or may be taken ; and (v) a claim of a pending patent application under the Patent Rights, which claim has been subject to prosecution for protection for no more than five years.

2. Exclusive License.

a. LIMR hereby grants to Company an exclusive, world-wide, royalty-bearing license ("License") under the LIMR Technology and the Patent Rights for LIMR Technology described in **[*]** and the Patent Rights to make, have made, use and/or sell Licensed Product in the field of human and animal therapeutics and diagnostics (the "Field"). Notwithstanding the foregoing, LIMR expressly reserves a non-transferable royalty-free right to use the Patent Rights and LIMR Technology in the Field itself, including use by its staff and researchers, for non-commercial educational and research purposes only. LIMR agrees to notify NewLink and provide NewLink a "first look" at any additional research findings that directly result from the use of the technology described in **[*]**.

b. RAND Compounds. Pursuant to and subject to the terms of the RAND Agreement between LIMR and the National Cancer Institute ("NCI") of the National Institutes of Health (NCI Contract No. High-Throughput Screening for Inhibitors of Indoleamine 2,3-dioxygenase (IDO)), the IDO inhibitory compounds that are identified by an ongoing screen of the compound collection at the NCI will be shared with NewLink.

3. Sublicenses. Company and its Affiliate(s) shall have the right to grant sublicenses to third parties under LIMR Technology and Patent Rights to make, have made, use and sell the Licensed Products. Such sublicenses shall be in writing and expressly subject to the terms of this Agreement. Any sublicense agreement that does not materially conform to this Agreement shall constitute a material breach of this Agreement by Company. Company agrees to be

responsible for the performance hereunder by its sub licensees. At LIMR's request, Company will provide LIMR with a copy of each sublicense in order to allow LIMR to audit such sublicenses to assure conformity with the Agreement. If LIMR performs such a review on any sublicense agreements, those audited agreements, not including any subsequent amendments or changes to the agreements, shall be deemed to conform to this Agreement. Upon termination of this Agreement, any such sublicenses will revert directly to LIMR, which shall have the right to cancel any such sublicense if such sublicensee is not then in compliance with the terms of its sublicense and the terms of this Agreement.

4. Term and Termination. The Term of this Agreement shall terminate upon expiration of the last to expire Valid Claim included in the Patent Rights. In addition, the Agreement may terminate earlier than the end of the Term under the following circumstances:

A. If NewLink is unable to achieve any of the milestones within the time periods set forth in Article 10, then LIMR shall, in accordance with the terms of this paragraph 4, have the right and option to reduce the NewLink's exclusive license to a nonexclusive license or revoke the license in its entirety, provided that prior to making this determination, LIMR shall

1. Give NewLink written notice of perceived failure to meet a milestone, describing the failure, describing the preferred method of cure and the proposed action to be taken by LIMR in the event of non-cure in writing at the address listed within this Agreement.

2. Provide NewLink a 90-day cure period during which NewLink shall be allowed to establish that it has met or will meet the milestones.

B. LIMR may terminate this Agreement immediately by providing NewLink written notice of termination, if

1. NewLink ceases to function as a going concern;

2. a petition or action is filed or taken by or against NewLink under any insolvency or bankruptcy law that is not dismissed within sixty (60) days;

3. a receiver, assignee or other liquidating officer is appointed for all or substantially all of the assets of NewLink; or

4. NewLink makes an assignment for the benefit of creditors.

C. If NewLink fails to make any payment whatsoever due and payable to LIMR hereunder, LIMR shall have the right to terminate this Agreement effective on thirty (30) days written notice, unless, NewLink shall make all such payments to LIMR within said thirty (30) day period provided that the payments demanded by LIMR are not disputed by NewLink. In that event, the parties shall have 90 days to solve the dispute at the end of which they shall submit to binding arbitration.

D. NewLink shall have the right to terminate this Agreement at any time on 90 days' notice to LIMR, and upon payment of all amounts due LIMR

through the effective date of the termination. In the event NewLink terminates the Agreement, all rights and obligations hereunder revert to LIMR.

E. Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. NewLink and any sub licensee thereof may, however, after the effective date of such

termination, sell all LICENSED PRODUCTS, and complete LICENSED PRODUCTS in the process of manufacture at the time of such termination and sell the same, provided that NewLink shall make the payments to LIMR as required by Articles 8 & 9 of this Agreement and shall submit the reports as required by Article 12 hereof.

5. Ownership. LIMR represents that it owns the rights to the LIMR Technology and the Patent Rights and has the right to convey the LIMR Technology and the Patent Rights to Company.

6. Patent Prosecution: NewLink shall be responsible, at its sole cost and expense, for the preparation, filing, prosecution and maintenance of any patent applications filed by and patents issued to LIMR as assignee under the Patent Rights pursuant to this Agreement. Upon execution of this Agreement, LIMR will make no further patent prosecution decisions and shall not incur additional expenses with respect to the Patent Rights without prior written consent of NewLink, which shall not be unreasonably withheld. With respect to costs incurred prior to execution of this Agreement, NewLink shall reimburse LIMR provided LIMR has provided NewLink with appropriate documentation outlining the costs incurred.

7. License Fee.

a. Initial Fee. Upon the Effective Date, NewLink shall pay LIMR a License Initiation Fee of **[*]**.

b. Annual Fee. NewLink shall pay LIMR an annual license fee of **[*]** due on each anniversary of the Effective Date.

8. Royalty: Company shall pay LIMR an earned royalty of **[*]** based on the value of Net Sales of the Licensed Products, unless additional royalties must be paid for another technology to allow use of Licensed Products in humans. In the event additional technologies must be licensed (e.g. formulation, cross linking) by NewLink from any third party, NewLink shall be entitled to offset against royalties otherwise due to LIMR **[*]**; provided, however, in no event shall NewLink pay LIMR a **[*]** royalty of less than **[*]**. NewLink agrees to pay LIMR and **[*]**, the potential licensor of related technologies, a total **[*]** royalty of **[*]**. If the aggregate of the **[*]** royalties paid to LIMR and **[*]** is less than **[*]**, NewLink shall pay LIMR the additional percentage amount necessary to equal an aggregate **[*]** royalty of **[*]**. In the event NewLink sublicenses the Licensed Product,

NewLink shall pay LIMR an earned royalty of **[*]** of any Consideration received by NewLink for the sublicense during the Term.

9. Payment: Royalties shall be payable by NewLink quarterly in U.S. dollars within thirty (30) days of the end of the calendar quarter. NewLink shall render quarterly reports to LIMR on or before the last day of April, July, October, and January showing the amount of Net Sales received by NewLink during the most recently concluded fiscal quarter and the appropriate Royalties due to LIMR. Each such report shall be accompanied by payment of the Royalties due for such fiscal quarter. NewLink shall provide LIMR audited annual financials within 30 days of completion of NewLink's audit, after the first commercial sale of any Licensed Product. NewLink shall pay estimated royalties payments quarterly with an annual reconciliation and of all payments performed within 30 days of receipt of audited numbers.

10. Milestones and Associated Payments: NewLink has represented to LIMR, to induce LIMR to issue this exclusive license, that it will commit itself to a diligent program of developing and exploiting Licensed Product(s) so that public utilization will result there from. As evidence thereof, Company shall adhere to the following milestones:

	Milestone	Payment
1	NewLink will **[*]** within **[*]**	None
2	NewLink will **[*]** within **[*]**	NewLink shall pay LIMR **[*]** upon **[*]**.
3	Once **[*]** NewLink shall **[*]**	NewLink shall pay LIMR **[*]** upon **[*]**.
4	Upon **[*]**, NewLink shall **[*]**	NewLink shall pay LIMR **[*]** upon **[*]**.
5	**[*]**. NewLink shall **[*]** within **[*]**.	NewLink shall pay LIMR **[*]** at the **[*]**.

All milestone fees are payable only once, regardless of the number of times the milestone is achieved and regardless of the number of License Products developed by NewLink.

11. Reports and Accounting. NewLink shall report to LIMR once a year during which time it describes its product development, financial information and milestone status.

12. Indemnity. Company shall defend and indemnify and hold LIMR, its affiliates, parent corporation, trustees, officers, agents and employees (the "Indemnitees") harmless from any judgments and other liabilities based upon claims or causes of action brought by a third party against LIMR or its employees which arise out of **[*]**, or from the **[*]**, except to the extent that such judgments or liabilities arise in whole or in part from **[*]**, provided that LIMR promptly notifies Company of any such claim coming to its attention and that it cooperates with Company in the defense of such claim. If any such claims or causes of action are made, Company's counsel, subject to LIMR's approval,

which shall not be unreasonably withheld, shall defend LIMR. LIMR reserves the right to be represented by its own counsel at its own expense.

13. Insurance. At such time as any product, process, service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Company or by a sub licensee, Affiliate or agent of Company, Company shall at its sole cost and expense, procure and maintain comprehensive general liability insurance in amounts not less than $3,000,000 per incident and naming the Indemnitees as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for Company's indemnification under this Agreement. If Company elects to self-insure all or part of the limits described above (including deductibles or retentions

which are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to LIMR and Main Line Health Vice President Insurance. Such insurance will be considered primary as to any other valid and collectible insurance, but only as to acts of the named insured. The minimum amounts of insurance coverage required shall not be construed to create a limit of Company's liability with respect to its indemnification under this Agreement. Company shall provide LIMR with written evidence of such insurance upon request of LIMR. Company shall provide LIMR with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if Company does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, LIMR shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice or any additional waiting periods. Company shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (I) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Company or by a sub licensee, Affiliate or agent of Company and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than fifteen (15) years.

14. Mutual Confidentiality. Company and LIMR realize that certain information received by one party from the other pursuant to this Agreement shall be confidential. It is therefore agreed that **any information received** by one party from the other should be clearly designated in writing as "**CONFIDENTIAL**" at the time of transfer, shall not be disclosed by either party to any third party and shall not be used by either party for purposes other than those contemplated by this Agreement. Any information exchanged by the parties under this Agreement shall remain confidential for a period of three (3) years from the termination of the Agreement, unless or until —

a. Said information shall become known to third parties not under any obligation of confidentiality to the disclosing party, or shall become publicly known through no fault of the receiving party, or

b. Said information was already in the receiving party's possession prior to the disclosure of said information to the receiving party, except in cases when the information has been covered by a preexisting Confidentiality Agreement, or

c. Said information shall be subsequently disclosed to the receiving party, by a third party not under any obligation of confidentiality to the disclosing party, or

d. Said information is approved for disclosure by prior written consent of the disclosing party, or

e. Said information is required to be disclosed by court order or governmental law or regulation, provided that the receiving party gives the disclosing party

prompt notice of any such requirement and cooperates with the disclosing party in attempting to limit such disclosure.

15. Disclaimer. Nothing contained in this Agreement shall be construed as:

A. a warranty or representation by LIMR as to the validity or scope of any Patent Rights;

B. a warranty or representation that any Licensed Products manufactured, used or sold will be free from infringement of patents, copyrights, or third parties, except that LIMR represents that it has no knowledge of any existing issued patents or copyrights which might be infringed;

C. **LIMR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF LICENSED PRODUCTS.**

16. Technical Assistance. Throughout the term of the Agreement, LIMR agrees to permit Company and its designees to consult with its employees and agents regarding developments and enhancements made after the Effective Date relating to the Licensed Products, at such times and places as may be mutually agreed upon; provided that Company agrees to limit such consultation to five (5) employee-investigator hours per week and make suitable arrangements directly with LIMR employees and agents and to compensate for such consultation.

17. Name. Company shall not use and shall not permit to be used by any other person or entity the name or logo of LIMR nor any adaptation thereof, or the name of LIMR's employees, in any advertising, promotional or sales literature, or for any other purpose without prior written permission of LIMR.

18. Governing Law. This Agreement shall be construed, governed, interpreted and enforced according to the laws of the Commonwealth of Pennsylvania.

19. Notices. Any notice or communication required or permitted to be given by either party hereunder, shall be deemed sufficiently given, if mailed by certified mail, return receipt requested, and addressed to the party to whom notice is given as follows:

If to LIMR:

Karen Knudsen, Ph.D.
Director of Scientific Administration
Lankenau Institute for Medical Research
100 E. Lancaster Avenue
Wynnewood, PA 19096

With a Copy to:

Office of the General Counsel
Main Line Health
130 So. Bryn Mawr Avenue
Bryn Mawr, PA 19010

If to NewLink:

Dr. Nick Vahanian
Chief Medical and Operations Officer
2901 South Loop Drive
Suite 3900
Ames, Iowa 50010

20. Assignment. Neither party shall assign or transfer this Agreement without the express prior written consent of the other, such consent not to be unreasonably withheld. For purposes of this Agreement, an assignment or transfer of this Agreement by NewLink shall be deemed to occur in connection with (a) an express assignment or transfer, (b) a general assignment for the benefit of creditors or in connection with any bankruptcy or other debtor relief law, (c) any merger or consolidation to which NewLink is a party, regardless of whether NewLink is the surviving corporation, or (d) any other transaction pursuant to which a change would occur in the "ultimate parent entity" of NewLink. Notwithstanding the foregoing, an assignment of this Agreement by NewLink in connection with the transfer of all or substantially all of its assets or equity, or by reason of acquisition, merger, consolidation or operation of law shall not require LIMR's consent.

21. Entire Agreement. This Agreement represents the entire agreement between the parties as of the effective date hereof, and may only be subsequently altered or modified by an instrument in writing. This Agreement cancels and supersedes any and all prior oral or written agreements between the parties that relate to the subject matter of this Agreement.

22. Mediation and Arbitration. Both parties agree that they shall attempt to resolve any dispute arising from this Agreement through mediation. Both parties agree that at least one company employee, capable of negotiating an agreement on behalf of his company, shall, within three weeks of receipt of written notification of a dispute, meet with at least one employee of the other party who is also capable of negotiating an agreement on behalf of his company. If no agreement can be reached, both parties agree to meet again within a four week

period after the initial meeting to negotiate in good faith to resolve the dispute. If no agreement can be reached after this second meeting, both parties agree to submit the dispute to binding arbitration under the Rules of The American Arbitration Association before a panel of three arbitrators.

23. Waiver. A failure by one of the parties to this Agreement to assert its rights for or upon any breach or default of this Agreement shall not be deemed a waiver of such rights nor shall any such waiver be implied from acceptance of any payment. No such failure or waiver in writing by any one of the parties hereto with respect to any rights, shall extend to or affect any subsequent breach or impair any right consequent thereon.

24. Severability. The parties agree that it is the intention of neither party to violate any public policy, statutory or common laws, and governmental or supranational regulations; that if any sentence, paragraph, clause or combination of the same is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

25. Marking. Company agrees to mark the Licensed Products in the United States with all applicable U.S. and state Trademarks, and U.S. Patent numbers.

26. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not constitute a part hereof.

Lankenau Institute for Medical Research		NewLink Genetics Corporation	
By:	/s/ Edward L. Jones, Jr.	Name:	/s/ Nicholas N. Vahanian
Title:	Chairman	Title:	Chief Medical and Operations Officer
Date:	July 8, 2005	Date:	July 7, 2005

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (the "Agreement") is made and entered into by and between **LANKENAU INSTITUTE FOR MEDICAL RESEARCH** ("LIMR") and **NEWLINK GENETICS CORPORATION** ("NewLink") for the licensing of certain intellectual property rights to NewLink, effective on this day of October, 2007 (the "Effective Date").

WHEREAS, LIMR owns certain technology and intellectual property rights developed by its employee(s) relating to inhibitors of Indoleamine 2, 3 Dioxygenase -2 ("IDO-2"), and

WHEREAS, LIMR has filed certain non-provisional patent applications covering such IDO-2 inhibitors and related inventions; and

WHEREAS, NewLink and LIMR intend to enter into a Collaborative Research and Development Agreement ("CRADA") covering further research to be conducted in cooperation with, and funded by, NewLink regarding inhibitors of IDO-2 (the "Sponsored Research"), to be conducted by Dr. George Prendergast at LIMR in collaboration with Dr. Michael William Malachowski in the Department of Chemistry at Bryn Mawr College **(**the "Investigators"), and LIMR shall provide NewLink with a copy of the term sheet on which LIMR's agreement with the Investigators will be based and a copy of the final agreement with the Investigators, subject to NewLink keeping such term sheet and final agreement confidential. ; and

WHEREAS, NewLink would like to obtain the exclusive**,** worldwide license rights from LIMR, and LIMR desires to grant such rights to NewLink, under such technology and intellectual property of LIMR, and under any improvements or derivatives thereof developed by LIMR, including resulting from the Sponsored Research, for the purpose of developing the technology into marketable therapeutic or diagnostic products;

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Definitions.

a. Affiliate(s). "Affiliate" means, with respect to NewLink, any individual, company or other business entity, in whatever country organized, that directly or indirectly controls, is controlled by, or is under common control with NewLink. For purposes of this Agreement, the term "control" (with correlative meanings for the terms "controlled by" and "under common with") shall mean that the applicable individual, company or entity owns, directly or indirectly, more than thirty-three percent (33%) of the voting stock or equity of NewLink, or otherwise has the ability to direct and manage the business affairs of NewLink (whether through contract or otherwise).

b. Consideration. Subject to the other provisions of this Agreement, "Consideration" shall mean any and all revenues or payments in-kind received by NewLink or its Affiliates from a Sublicensee (as defined in Article 3) as consideration for the grant by NewLink of a sublicense under the rights granted to

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NewLink by LIMR pursuant to Article 2(a) hereof, *but excluding* sums or amounts received: (i) for the purchase of an equity interest in NewLink (which for purposes of this Agreement shall be valued at fair market value at the time of receipt by NewLink); (ii) as payments or reimbursements for research and development work performed by or on behalf of NewLink (which reimbursement may be in the form of reasonable and typical FTE rates); (iii) for purchase or supply of Licensed Product; and (iv) as a loan, or as reimbursement of patent prosecution costs, or as payment of a share of amounts recovered in enforcing a patent or other intellectual property rights. Furthermore, if NewLink or an Affiliate receives from a Sublicensee payments or revenue, and such payments or revenue is in consideration both for the grant of a sublicense under the licenses granted to NewLink hereunder as well as for the grant of a license or sublicense to other technology controlled by NewLink but not acquired from LIMR under this Agreement, then the "Consideration", for purposes of this Agreement, shall be deemed to be such payments or revenue multiplied by a percentage that fairly represents, as reasonably determined and mutually agreed upon by the parties, the percentage contribution of the LIMR Technology and the Patent Rights to the total value of the rights licenses or sublicensed by NewLink or its Affiliate to such Sublicensee.

c. Improvements. "Improvement" shall mean any improvement, modification, derivative, and/or enhancement of the LIMR Technology or the Patent Rights developed, acquired or otherwise controlled by LIMR at any time after the Effective Date.

d. Licensed Product. "Licensed Product" shall mean any article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered or claimed by a Valid Claim within the Patent Rights. For clarity, a "Licensed Product" shall not include other product or material that (a) is used in combination with Licensed Product, and (b) does not constitute an article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered or claimed by a Valid Claim within the Patent Rights.

e. LIMR Technology. "LIMR Technology" shall mean the technology and/or know-how owned or controlled by LIMR that specifically relates to the subject matter of the Patent Rights or is otherwise necessary or useful for the practice of the Patent Rights.

f. Net Sales. "Net Sales" shall mean the gross consideration actually received or collected by NewLink and/or any Affiliate from the transfer, sale or other commercial distribution of any Licensed Product to a third party customer, less:

(1) revenue credited or rebated on returns and allowances, and bad debts;

(2) discounts, in amounts customary in the trade and to the extent actually granted, for quantity purchases, for prompt payments and for wholesalers and distributors;

(3) transportation, shipping, insurance and delivery charges or allowances;

(4) customs, duties;

(5) sales, use, excise, value-added and other taxes (other than the taxes on the income of the selling party or NewLink) or other governmental charges measured by sales;

(6) governmental and managed care rebates or chargebacks to the extent actually incurred or allowed with respect to Licensed Product sold during the relevant time period to group purchasing organizations, hospitals, or other buying groups; and

(7) retroactive price reductions that are actually allowed or granted.

Sales between or among NewLink and its Affiliates will be excluded from the computation of Net Sales, but the subsequent final sales of such Licensed Product to third parties by NewLink or its Affiliates will be included in the computation of Net Sales. In addition, transfers or dispositions of Licensed Products in commercially reasonably quantities for nominal consideration the use of which is restricted to either charitable, sampling or promotional purposes or for preclinical, clinical, manufacturing (without sale), scale-up, regulatory or governmental purposes shall not be considered a "sale" or "other commercial disposition" and shall not be included for purposes of calculating Net Sales under this Agreement. Sales of Licensed Products to Sublicensees shall be included in "Net Sales", as are the royalty payments to NewLink (or its Affiliate) by Sublicensees on resale of such Licensed Product, the intent being that LIMR shall receive a royalty or other share or payment on any and all consideration received by NewLink or its Affiliates hereunder, unless expressly excluded in this Agreement.

If NewLink (or its Affiliate) sells a Licensed Product in combination with another active component or ingredient, which is not itself a Licensed Product (a "**Combination Product**"), for one selling price, then the "Net Sales of such Combination Product, for the purpose of determining the royalty owed, shall be the Net Sales resulting from such sale, as set forth above, multiplied by a factor that reflects the fair market value, in such Combination Product, of the Licensed Product therein, compared to the total market value of the Combination Product including its other active components or ingredients, such factor to be determined reasonably and in good faith by NewLink and LIMR.

g. Patent Rights. "Patent Rights" shall mean (a) the patent applications identified on **Exhibit A** of this Agreement; (b) all patents and patent applications of LIMR

covering or claiming any improvement, modification, derivative, and or enhancement of the LIMR Technology or of any of the patent applications or rights or foreign counterparts described in subclauses (a), (c), (d) or (e) of this definition; (c) all continuing patent applications (including divisional, substitution, continuations and continuations-in-part) based on any of the foregoing applications; (d) all rights and interest held, acquired or otherwise controlled by LIMR in and to any patents issuing on any of the foregoing applications (including any reexaminations, reissues, renewals, inventors certifications, and extensions thereof); and (e) all foreign counterparts worldwide of any such patent applications and patents.

h. Research Aims. "Research Aims" shall have the meaning ascribed to such term in the CRADA, as summarized in Exhibit B of this Agreement.

i. Successful Completion. "Successful Completion" of a particular clinical trial means that such trial has been completed on sufficient numbers of subjects to meet the regulatory requirements for proceeding to the next phase of clinical trials, the final report analyzing the data from such subjects in such trial has been completed, and the results of such data support initiating the next phase of clinical trials on the drug studied in such trial.

j. Valid Claim. A "Valid Claim" means (i) a claim of an issued patent in the Patent Rights that (a) has not expired or been abandoned; (b) has not been disclaimed; (c) has not been canceled or superseded, or if cancelled or superseded, has not been reasserted; (d) has not been revoked, held invalid or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such claim in any country in which such patent may have issued (from which no further appeal has or may be taken); and/or (e) abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written consent; or (ii) a claim included in a pending patent application under the Patent Rights, which claim is being actively prosecuted in accordance with this Agreement, has been subject to prosecution for protection for no more than five years and has not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority in such country (and from which no appeal is or can be taken), and/or abandoned in accordance with or as permitted by the terms of this Agreement by mutual written consent.

k. Future IDO Discoveries. "Future IDO Discoveries" means any new developments, inventions or discoveries created or developed by LIMR or its employees, agents, or subcontractors (such as by the Investigators) in connection with the Sponsored Research or otherwise that (a) relate directly to IDO-2 and/or inhibitors of IDO-2 and (b) are not covered or claimed by the Patent Rights and do not incorporate the LIMR Technology licensed under this Agreement. The discovery of **[*]** be considered Future IDO Discoveries.

l. Milestones.

(1) Scientific Milestones. "Scientific Milestone" means the successful completion of a Research Aim.

(2) Development Milestones. "Development Milestones" shall have the meaning ascribed to such term in Section 10(b) of this Agreement.

2. Exclusive License.

a. License Grant. Subject to the retained rights of LIMR and the government set forth in subsection 2(c) below, LIMR hereby grants to NewLink the exclusive, world-wide, royalty-bearing license, with the right to grant sublicenses, to use and practice the LIMR Technology and the Patent Rights in all fields and to make, have made, use, sell, offer for sale, and/or import Licensed Product in all fields (the "License").

With respect to any Licensed Products covered by Patent Rights that have been discovered using Federal funding, NewLink and its sublicensees shall comply (to the extent applicable) with the requirements of the Bayh-Dole Act which require that "any products embodying the invention or produced through the use of the subject invention will be manufactured substantially in the United States." (United States Code, Title 35, Part II, Chapter 18, Section 204), *except* if there is an exception to such requirement, and provided that LIMR shall use reasonable efforts, if reasonably requested by NewLink, to request and obtain an exception to such requirement.

b. RAND Compounds. Pursuant to and subject to the terms of the RAND Agreement between LIMR and the National Cancer Institute ("NCI") of the National Institutes of Health (NCI Contract No. High-Throughput Screening for Inhibitors of Indoleamine 2,3-dioxygenase (IDO)), the IDO inhibitory compounds that are identified by an ongoing screen of the compound collection at the NCI will be licensed to NewLink as Improvements.

c. Retained Rights. Notwithstanding the foregoing, LIMR expressly reserves a non-exclusive, non-transferable, royalty-free right to use the Patent Rights and the LIMR Technology, including use by its staff and researchers, and affiliates for its internal non-commercial, educational and research purposes only, including without limitation the right of LIMR to publish its research, subject to the prior review by NewLink to the extent such publication would disclose confidential LIMR Technology licensed hereunder. LIMR shall temporarily refrain from publication for a reasonable period of time to accommodate any patent filings or other regulatory actions intended to protect any confidential LIMR Technology licensed hereunder, such period of time not to exceed

the later of **[*]** from (x) the date on which such confidential LIMR Technology was **[*]** or (y) the date on which such confidential LIMR Technology was **[*]**. Further, the licenses granted to NewLink in Section 2(a) are subject to certain rights reserved by the United States government pursuant to applicable law or regulation in any inventions in the Patent Rights made with federal funding pursuant to National Institutes of Health Grant No. RO1-CA109542.

3. Sublicenses. NewLink and its Affiliates shall have the right to grant sublicenses to third parties (each, a "Sublicensee") under the LIMR Technology and Patent Rights (with the further rights to sublicense) for all purposes including to research, develop, make, have made, use and sell the Licensed Products. Such sublicenses shall be in writing and expressly subject to the terms of this Agreement, and shall not grant rights under the Patent Rights that exceed the scope of the rights expressly granted under this Agreement. Any such sublicense agreement that is materially inconsistent with this Agreement shall constitute a material breach of this Agreement by Company. NewLink agrees to require that its Sublicensees must not violate the terms of this Agreement, and that such Sublicensees shall do the same with respect to any further subsublicenses, and NewLink shall use commercially reasonable efforts to enforce such obligations for the benefit of LIMR. At LIMR's request, NewLink will provide LIMR with a copy of each sublicense and subsublicense in order to allow LIMR to review such sublicenses and subsublicenses to assure consistency with this Agreement (which copy may be redacted to delete any confidential information that does not relate to the Patent Rights or LIMR Technology or the sublicense of rights thereunder). If LIMR performs such a review on any sublicense or subsublicense agreement, those agreements reviewed by LIMR, not including any subsequent amendments or changes to the agreements, shall be deemed to conform to this Agreement unless LIMR has raised an objection to one or more of such sublicense or subsublicense agreements. Upon termination of this Agreement in compliance with the notice and other provisions of this Agreement, and subject to Section 4(e) below, any such sublicenses between NewLink and its sublicensees will remain in effectand be assigned directly to LIMR, which shall have the right to cancel any such sublicense if such sublicensee is not then in compliance with the terms of its sublicense and he applicable terms of this Agreement. Notwithstanding the foregoing, LIMR shall not be responsible for any obligation of NewLink under any such agreement which obligation accrued prior to the date of such assignment and if there is any such unperformed obligation which is ongoing or which affects the obligations of the subsublicensee or its ability to perform, LIMR may elect to cancel such sublicense agreement, without liability, upon written notice to such subsublicensee. Upon such a cancellation], the subsublicensee may sell all Licensed Products in its inventory and [complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided it is not in default under its subsublicense agreement and further provided it pays to LIMR all payments required to be paid to the sublicensor thereunder and provides one or more accountings of all such sales to LIMR (i) within thirty (30) days of LIMR's

request therefore and (ii) within thirty days after the last such sale, such accountings to be certified as true, complete and correct by such sublicensee's chief financial officer.

4. Term and Termination. The term of this Agreement shall commence as of the Effective Date and shall stay in effect until the last to expire issued Valid Claim covering Licensed Products included in the Patent Rights, unless otherwise terminated earlier as provided below in this Article 4 (collectively, the "Term").

a. If LIMR believes in good faith that NewLink has materially breached its obligations under Section 10(a), then LIMR shall, in accordance with the terms of this paragraph 4, have the right and option to reduce NewLink's exclusive License to a nonexclusive license or revoke the License in its entirety (by terminating the Agreement), provided that prior to taking this action:

(1) LIMR shall provide NewLink written notice of the perceived breach, describing in detail the basis for LEVIR's belief that such perceived breach has occurred, describing the preferred method of cure and the proposed action to be taken by LIMR in the event

of non-cure; and

(2) NewLink shal+l have ninety (90) days to establish that it has met or will, within such ninety (90) day period, meet the applicable obligations; if the parties are still in dispute as to whether NewLink has met such obligations or cured such breach within ninety (90) days after receipt of notice from LIMR, the dispute will be submitted to binding arbitration in accordance with Section 26(b) of this Agreement, and if such arbitration determines that NewLink materially breached its obligations under Section 10(a) and did not cure such breach, then LIMR shall have the option to terminate this Agreement or to convert the License granted to NewLink in Section 2(a) to a non-exclusive license, in each case, upon prior written notice to NewLink.

b. LIMR may terminate this Agreement immediately by providing NewLink written notice of termination, if:

(1) NewLink ceases to function as a going concern;

(2) a bankruptcy petition or action is filed or taken by or against NewLink under any United States bankruptcy law;

(3) a receiver, assignee or other liquidating officer is appointed with control for all or substantially all of the assets of NewLink; or

(4) NewLink makes an assignment for the benefit of creditors of all or substantially all its assets;

provided, that, in the case of subclauses (b)(2), (3) or (4) above, such aforementioned circumstance is not remedied, dismissed or stayed within sixty (60) days of LIMR's notice of its intent to terminate this Agreement;

Notwithstanding anything in Sections 4(a) or (b) or 26 to the contrary, at any time that LIMR or NewLink believes that the other party has defaulted under this Agreement and that such default will irreparably harm such party, in addition to its rights under this Agreement and at law, such party shall have the right to seek all applicable equitable remedies.

c. If NewLink fails to make any payment whatsoever due and payable to LIMR hereunder, LIMR shall have the right to terminate this Agreement effective on thirty (30) days written notice, unless NewLink shall make all such payments to LIMR within said thirty (30) day period, and provided that the payments demanded by LIMR are not disputed by NewLink. In the event of a dispute of such payments by NewLink, the parties shall use good faith efforts to resolve the dispute, which if not resolved by the end of 90 days either party may submit the dispute to binding arbitration pursuant to Section 26(b). Any disputed payments submitted to arbitration hereunder shall not be deemed due and payable unless and until determined due by the arbitrator under Section 26(b).

d. NewLink shall have the right to terminate this Agreement at any time on 90 days' prior written notice to LIMR, provided that NewLink shall remain obligated to complete payment of all amounts that have accrued and are owed to LIMR through the effective date of the termination. In the event NewLink terminates the Agreement, the license granted hereunder shall be deemed terminated, and all rights with respect to the subject matter thereof revert to LIMR and all further obligations of NewLink to LIMR (except for obligations accrued prior to such termination) shall automatically be terminated.

e. Upon expiration or termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that has accrued prior to the effective date of such termination. NewLink and any Sublicensee thereof may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same**,** provided that NewLink shall make the payments to LIMR as required by Articles 8 & 9 of this Agreement and shall submit the reports as required by Article 12 hereof.

f. Sections 4(e), 4(f), 8(b) (but solely with respect to sales made pursuant to Section 4(e)), 16 (solely for the period specified therein), 14, 15, 21, 22, 23, 24 and 26 shall survive termination or expiration of this Agreement.

5. Ownership. LIMR represents and warrants to NewLink that LIMR owns the rights to the LIMR Technology and the Patent Rights and has the right to license the LIMR

Technology and the Patent Rights to NewLink, subject to the rights retained by the United States government and LIMR as described in Section 2(c).

6. Patent Prosecution. Commencing on the Effective Date, NewLink shall have the right and responsibility, at its expense and in its reasonable discretion, for the preparation, filing, prosecution and maintenance of any patent applications and patents included in the Patent Rights, in consultation with LIMR. NewLink shall provide LIMR the right to review and comment upon such patent applications prior to filing, and on all communications with patent offices in all applicable countries and jurisdictions, the selection of countries for filing of patent applications, responses to office actions, and other substantive patent documents prior to filing and the right to have such documents revised prior to filing to reflect such comments. Promptly after the Effective Date, LIMR will transfer to NewLink (or its selected counsel) all patent prosecution files for the Patent Rights, shall provide to NewLink such executed documents or instruments as needed for NewLink to undertake such prosecution efforts, and shall provide NewLink all reasonable assistance in such prosecution. NewLink shall reimburse LIMR for the reasonable out-of-pocket costs, based on detailed invoices of such costs, actually incurred in conducting such prosecution and maintenance of the Patent Rights prior to the Effective Date, not to exceed $17,000; provided that LIMR has provided NewLink with an invoice for such costs together with appropriate documentation outlining the costs incurred. LIMR shall provide NewLink with all information necessary or useful its filings and prosecution of such Patent Rights and shall cooperate fully with NewLink so as to maximize NewLink's rights. NewLink shall not abandon or opt not to file any patent or patent application included in the Patent Rights without the prior notice to LIMR. NewLink may elect in writing to cease the continued prosecution or maintenance of particular Patent Right in a country, and on such notice NewLink shall no longer have any further rights or responsibility for the such prosecution or maintenance, or obligation to pay any amounts therefore, or any further rights under such specific Patent Right in such country,

and LIMR may in its discretion continue such prosecution Any such notice shall be given by NewLink to LIMR in sufficient time to enable LIMR an adequate time period to protect its rights, but in no case less than three (3) months prior the filing deadline imposed or promulgated by any governing or regulatory authority for filing any such protective document.

7. License Fee.

a. Initial Fee. Upon the Effective Date, NewLink shall pay LIMR an initial one-time fee of **[*]**.

b. Annual Fee. NewLink shall pay LIMR an annual license maintenance fee of **[*]** due on or before each anniversary of the Effective Date during the Term.

8. Royalty; Sublicense Payments.

a. NewLink shall pay LIMR a royalty in an amount equal to **[*]** of the Net Sales of the Licensed Products in **[*]** where the **[*]**, unless additional royalties must be paid by NewLink for another technology to allow use of Licensed Products as provided in subsection (b) below. Royalties payable under this Section 7(a) shall be payable during the Term on a country-by-country basis.

b. In the event one or more additional technologies (including any patents related thereto) must be licensed (e.g. formulation, cross linking) by NewLink, its Affiliates, and/or Sublicensees from any third party to develop, make, use, import, sell, offer for sale, or import a Licensed Product in any country, NewLink shall be entitled to **[*]** royalties otherwise due to LIMR hereunder an amount **[*]**; provided, however, that in no event shall NewLink pay LIMR a royalty of less than **[*]** of Net Sales.

c. If NewLink grants a sublicense, under the License rights granted under this Agreement to NewLink, to a Sublicensee pursuant to Article 3 hereof, NewLink shall pay LIMR **[*]** of any Consideration received by NewLink from such Sublicensee, for each such sublicense during the Term.

d. No more than one royalty payment shall be due with respect to a sale of a particular Licensed Product. No multiple royalties shall be payable because any Licensed Product, or its manufacture, sale or use is covered by more than one Valid Claim in a given country.

9. Payment of Royalties. Royalties and sublicense payments shall be payable by NewLink quarterly in U.S. dollars within forty-five (45) days of the end of the calendar quarter. NewLink shall render quarterly reports to LIMR on or before the last day of April, July, October, and January, as applicable, showing the amount of Net Sales received by NewLink during the most recently concluded fiscal quarter and the appropriate royalties and sublicense payments due to LIMR certified by NewLink's chief financial officer (or comparable financial officer) as true, correct and complete. Each such report shall be accompanied by payment of the royalties and/or sublicense payments due for such fiscal quarter. After the first commercial sale of any Licensed Product pursuant to this Agreement, and upon LIMR' s request and at its expense, NewLink shall provide LIMR with copies of NewLink's then-existing standard audited financial statements covering the royalties and sublicense payments due under this Agreement within thirty (30) days of LIMR's request. NewLink shall pay estimated royalties payments quarterly with an annual reconciliation and of all payments performed within 30 days of receipt of audited numbers. For the purpose of determining royalties payable under this Agreement, any Consideration NewLink receives from Sublicensees in currencies other than U.S. dollars and any Net Sales denominated in currencies other than U.S. dollars shall be converted into U.S. dollars at the same conversion rate that NewLink actually receives on such conversion at the time of the transaction in question which gave rise the Consideration.

10. Diligence; Milestones and Associated Payments.

a. Diligence. NewLink has represented to LIMR, to induce LIMR to issue this exclusive license, that it will commit itself to a diligent program of developing and exploiting Licensed Product(s) so that public utilization will result there from. As part of the consideration for the exclusive license granted to NewLink hereunder, NewLink has agreed to use commercially reasonable efforts to develop and exploit Licensed Product.

It is understood and agreed by the parties that the actions by any Affiliate or Sublicensee may satisfy the above obligations.

b. Milestone Payments to LIMR.

(1) Upon achievement of each **[*]**, NewLink will pay to LIMR a one-time payment of **[*]**, for a maximum total payment of **[*]** for achievement of all **[*]**.

(2) NewLink will pay to LIMR **[*]** for the **[*]** a Licensed Product; **[*]** for the **[*]** a Licensed Product; **[*]** for the **[*]** a Licensed Product; and **[*]** for the **[*]** a Licensed Product (the "Development Milestones"). For clarity, each Development Milestone shall be payable only once under this Agreement.

c. Limitation on Payments for Dual Activity Products. NewLink and LIMR acknowledge that, due to the nature of IDO inhibitors, a particular Licensed Product may have activity in inhibiting both the IDO-2 target and also IDO-1 (such product, a "Dual Activity Product"). For any Dual Activity Product that is covered by the payment obligations under this Agreement, and ***also*** is subject to payment obligations (milestone payments and/or royalty payments) under the Exclusive License Agreement dated July 7, 2005 between the Parties, covering IDO-1 inhibitors (the "Prior License"), NewLink shall ***not*** owe payments under both agreements due to the achievement of the milestone event by, or sale of, such Dual Activity Product, ***but rather*** shall owe to LIMR the higher of the applicable milestone payment, or royalty payment, owed for such Dual Activity Product under the terms of either the Agreement and the Prior License (based on the particular event

or sale). The foregoing shall apply to all obligations under the Prior Agreement with respect to any product covered by such agreement that is a Dual Activity Product.

For the purposes of determining which licensing agreement — either this Agreement or the Prior License (as defined above) — will govern and regulate a particular inhibitor compound, each such compound will be classified either as an IDO1-specific inhibitor, an IDO2-specific inhibitor or a Dual Activity Product (an IDO1/IDO2 dual inhibitor) based **[*]**. A compound will be considered a Dual Activity Product when the **[*]** and the **[*]** are **[*]**. If the **[*]**, then the **[*]** will determine whether the compound is an IDO1-specific inhibitor or an IDO-2 specific inhibitor.

11. CRADA. Concurrently with entry into this Agreement, the parties agree to the obligations set forth in Exhibit B, which is hereby made a part hereof of this Agreement, pursuant to which NewLink will provide certain funding to LIMR in support of the Sponsored Research to be conducted by the Investigators. Under such CRADA, NewLink may renew the Sponsored Research (Newlink shall base its election upon the research results and other potential corporate limitations) for additional years at an annual budget to be based on scientific needs and approved by NewLink; **[*]** described in Exhibit B, in consideration for such funding LIMR agrees to **[*]** for Future IDO Discoveries as provided in Section 13 (b). The decision to renew the CRADA for additional years shall be made at least three months prior to the expiration date of the CRADA and shall based on a progress report submitted by LIMR to NewLink.

12. Reports and Accounting. NewLink shall provide to LIMR no less than once a year during the Term a written report regarding NewLink's product development, royalty and sublicense payment (i.e., receipt of Consideration) information with respect to Licensed Products and milestone status. The report shall be certified by an officer of NewLink as true, correct and complete. This report is in addition to the reports required under Section 9 hereof.

13. Exclusive Option to Future IDO Discoveries.

a. LIMR hereby grants NewLink the exclusive option to obtain an exclusive, worldwide, sublicensable license under LIMR's interests in and to any or all Future IDO Discoveries (including any patent rights or other intellectual property covering or appurtenant to such Future IDO Discoveries) for any and all purposes, including to develop, make, have made, use, sell, offer for sale, and import products. LIMR shall promptly disclose in writing to NewLink (or its designees) any Future IDO Discovery made or identified, including all relevant information relating to the Future IDO Discovery as reasonably needed for NewLink to evaluate whether to exercise the option. NewLink shall indicate its intention to exercise such option by notifying LIMR in writing within six (6) months after the disclosure of such Future IDO Discovery to NewLink hereunder (such period, the "Option Period" as to such Future IDO Discovery).

b. If NewLink exercises such option for a particular Future IDO Discovery disclosed by LIMR pursuant to Section 13(a) above, the parties will negotiate exclusively and in good faith the specific terms and conditions on which an exclusive (or if elected by NewLink, non-exclusive) license will be granted. Such license shall be on commercially reasonable terms typical for similar license agreements; provided, however, that should NewLink elect to renew the CRADA for additional years of funding **[*]**, LIMR **[*]** of any Future IDO Discovery. The **[*]** reduce the requirement of the payment of **[*]** as consideration for such license(s) (provided that, to the extent appropriate in a determination of **[*]**, NewLink's funding under the CRADA shall be taken into account in determining what is such **[*]**). The annual fees, royalties, and sublicensing fees associated with such license shall be based upon and be equivalent to the **[*]** of the underlying Future IDO Discovery, and any other reasonable terms and conditions, in each case, shall be negotiated by the parties in good faith. If the parties are unable, despite each party using good faith efforts, to agree upon the terms of such license within six (6) months following the date the option is exercised by NewLink with respect to a particular Future IDO Discovery, then the option as to Future IDO Discovery shall expire; provided, however, that in no event may LIMR enter into a license or other similar agreement with any third party with respect to such Future IDO Discovery on terms more favorable to such third party than those last offered to NewLink during the twenty-four (24) months immediately following such option expiration, unless LIMR has first offered to NewLink the right to obtain such license on such terms, and NewLink fails to accept such terms within thirty (30) days after receiving LIMR's offer.

14. Indemnity. NewLink shall defend and indemnify and hold LIMR, its parent corporations, affiliates, trustees, officers, agents and employees (the "Indemnitees") harmless from any judgments and other liabilities based upon claims or causes of action brought by a third party against any Indemnitee which arise out of alleged negligence in the development, manufacture or sale of Licensed Products by NewLink, its Affiliates or any Sublicensees, or from the use by the end users of Licensed Products, except to the extent that such judgments or liabilities arise in whole or in part from the gross negligence or willful misconduct of LIMR or its employees, provided that LIMR promptly notifies NewLink of any such claim coming to its attention and that it cooperates with NewLink in the defense of such claim. If any such claims or causes of action are made, NewLink counsel, the identity of whom LIMR does not have a reasonable objection, shall defend LIMR. If LIMR has a reasonable objection to the counsel selected by NewLink, LIMR and NewLink shall cooperate with each other reasonably and in good faith so that NewLink can engage legal counsel to whom LIMR does not have reasonable objection. LIMR reserves the right to be represented by its own counsel at its own expense.

15. Limitations of Liability. EXCEPT FOR THE INDEMNIFICATION OBLIGATIONS ABOVE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR

ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST REVENUES OR LOST PROFITS, WHETHER BASED ON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT OR OTHERWISE ARISING OUT OF THIS AGREEMENT, AND REGARDLESS OF WHETHER SUCH

PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING ANYTHING TO THE CONTRARY SET FORTH HEREIN, NEWLINK'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL BE LIMITED TO THE **[*]**.

16. Insurance. At such time as NewLink, its Affiliates, or Sublicensees, initiates or otherwise enters into clinical trials of any Licensed Product or commercially distributes or sells Licensed Products (other than for the purpose of obtaining regulatory approvals), NewLink shall at its sole cost and expense, procure and maintain comprehensive general liability insurance in amounts not less than $3,000,000 per incident and naming the Indemnitees (defined in Section 13(a) above) as additional insureds. LIMR may require such minimum requirements to be increased from time to time if the minimum amounts of such insurance carried by prudent companies in the general size of NewLink and in similar industries as NewLink is higher, so that NewLink will at all times carry commercially reasonable amounts of insurance. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for NewLink's indemnification under this Agreement. If NewLink elects to self-insure all or part of the limits described above (including deductibles or retentions, which are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to LIMR and Main Line Health Vice President Insurance in their sole and absolute discretion. Such insurance will be considered primary as to any other valid and collectible insurance, but only as to acts of the named insured. The minimum amounts of insurance coverage required shall not be construed to create a limit of NewLink's liability with respect to its indemnification and other obligations under this Agreement. NewLink shall provide LIMR with written evidence of such insurance promptly upon written request of LIMR. NewLink shall use commercially reasonable efforts to provide LIMR with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance. If NewLink does not obtain replacement insurance providing comparable coverage within sixty (60) days following the date of such cancellation, non-renewal or material change, LIMR shall have the right to terminate this Agreement effective at the end of such sixty (60) day period without notice or any additional waiting periods. NewLink shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any Licensed Product is being clinically tested, commercially distributed or sold by NewLink (or an agent on its behalf) or by a sublicensee, Affiliate and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than five (5) years.

17. Mutual Confidentiality. NewLink and LIMR realize that certain confidential or proprietary information disclosed by one party (the "disclosing party") to the other party (the "receiving party") pursuant to this Agreement ("Confidential Information" of the

disclosing party) shall be treated as confidential. For purposes of this Agreement, the term "Confidential Information" of a party means any of the following:

a. all information concerning the business or affairs of either party or its affiliates, including without limitation, all information relating to the LIMR Technology or to NewLink technology, the Patent Rights, the Licensed Product, the Future IDO Discoveries, and/or any and all existing and potential research parameters, program requirements, strategies, products, technology, know-how, information, data, processes, systems, inventions, developments, formulations, applications, and methods of rendition of services relating to any of the foregoing;

b. all information received from third parties and held in confidence by either party or its affiliates, or

c. all information pertaining to the proposed business relationship(s) and/or transactions(s) between the parties, including without limitation, the terms thereof (except that LIMR may disclose the terms of this Agreement to Bryn Mawr College or Professor Bill Malachowski or to their legal counsel to the extent LIMR deems such disclosure necessary or appropriate in connection with negotiating with them agreements related to this Agreement or to the Sponsored Research.

The Confidential Information of the disclosing party shall not be disclosed by the receiving party to any third party and shall not be used by the receiving party for purposes other than those contemplated by this Agreement without the prior written consent of the disclosing party. Any Confidential Information exchanged by the parties under this Agreement shall remain subject to such confidentiality and non-use obligations for a period of five (5) years from the termination or expiration of the Agreement. The confidentiality and non-use obligations under this Article 17 shall not apply to any information that:

a. Is or which later becomes publicly known through no fault of the receiving party, or

b. Is already in the receiving party's possession prior to the disclosure by the disclosing party to the receiving party as indicated in the receiving party's competent written records, or

c. Is subsequently disclosed to the receiving party, by a third party not under any obligation of confidentiality to the disclosing party, or

d. Is independently developed by the receiving party without use of the Confidential Information of disclosing party or any other information from the disclosing party that is protected by any other confidentiality obligations.

In addition, the receiving party may disclose specific Confidential Information of the other party to the extent such disclosure is required to be disclosed by court order or governmental law, rule or regulation, provided that the receiving party first gives the disclosing party prompt written

notice of any such requirement and cooperates with the disclosing party in attempting to limit or seek confidential treatment with respect to such disclosure of such Confidential Information.

The provisions of this Section 17 are subject to the publication rights of LIMR as described in Section 2(c) hereof.

18. Disclaimer. Except as expressly set forth in Section 5 hereof, nothing contained in this Agreement shall be construed as:

a. a warranty or representation by LIMR as to the validity or scope of any Patent Rights;

b. a warranty or representation that any Licensed Products manufactured, used or sold will be free from infringement of patents, copyrights, or third parties, except that LIMR represents that it has no knowledge of any existing issued patents or copyrights which might be infringed;

LIMR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF LICENSED PRODUCTS.

19. Third party Infringement.

a. Each party shall promptly notify the other party in writing of any alleged or actual infringement of the Patent Rights of which it becomes aware and which may adversely impact the rights of either party hereunder.

b. NewLink shall have the first right but not the obligation, at its expense, to bring an appropriate action against any person or entity directly or contributorily infringing the Patent Rights. LIMR shall cooperate reasonably with NewLink in such action, including by consenting to be named as a party to such action and furnishing a power of attorney upon request. Except as otherwise set forth in this Agreement, NewLink shall have sole control of the action brought by it; provided, however, that LIMR shall have the right to participate in such action against a third party infringer through counsel of its own choice and at its own expense.

c. In the event NewLink institutes legal action against an infringer hereunder, LIMR shall fully cooperate with and supply all assistance reasonably requested by NewLink,

including, without limitation, by using commercially reasonable efforts to have its employees testify and grant interviews when requested and to make available relevant records, papers, information, samples, specimens, and similar items upon request of NewLink LIMR shall render such cooperation at its own cost and expense ("LIMR's Costs"). NewLink shall keep LIMR reasonably informed of the progress of such action, and LIMR shall be entitled to be represented by counsel in connection with such action at its own expense.

d. NewLink shall bear the costs of all reasonable and customary expenses for such action (including attorneys' fees and expert fees). Any amounts paid to NewLink by third parties as a result of such action (in satisfaction of a judgment or pursuant to a settlement recovery) shall first be applied to the payment of NewLink's out-of-pocket expenses (including attorneys' fees and expert fees), second to LIMR's Costs, third to LIMR's other out-of-pocket expenses in connection with the matter (including attorneys' fees and experts fees), and then the balance of any such amounts **[*]**. NewLink shall have the right to settle any claims, but provided that if such settlement materially negatively affects LIMR's interests such settlement shall be only upon terms and conditions that are reasonably acceptable to LIMR, such reasonable acceptance to be confirmed by LIMR in writing prior to NewLink's agreement to such settlement.

e. If NewLink elects to abandon such an action other than pursuant to a settlement with the alleged infringer that is reasonably acceptable to LIMR, NewLink shall give timely notice to LIMR who, if it so desires, may continue the action; provided, however, that the sharing of expenses and any recovery in such suit shall be **[*]**. Any such notice shall be given by NewLink to LIMR in sufficient advance of the expiration of the applicable statute of limitations to enable LIMR an adequate time period to protect its rights, but in no case less than twelve (12) months prior to the expiration of such statute of limitations.

20. Technical Assistance. Throughout the term of the Agreement, LIMR agrees to permit NewLink and its designees to consult with its employees and agents regarding any Improvements or Future IDO Inventions made after the Effective Date relating to the Licensed Products, at such times and places as may be mutually agreed upon; provided that NewLink agrees to limit such consultation to five (5) employee-investigator hours per week and make suitable arrangements directly with LIMR employees and agents and to compensate for such consultation at LIMR's then-current rates as communicated to NewLink.

21. Name. NewLink shall not use and shall not permit to be used by any other person or entity the name or logo of LIMR nor any adaptation thereof, or the name of LIMR's employees, in any advertising, promotional or sales literature, or for any other purpose without prior written permission of LIMR, except as required by governmental authority or applicable law, and provided that the foregoing shall not prevent NewLink from disclosing to third parties the existence of this Agreement including the CRADA obligations.

22. Governing Law. This Agreement shall be construed, governed, interpreted and enforced according to the laws of the Commonwealth of Pennsylvania without reference to principles of conflicts of laws.

23. Notices. Any notice or communication required or permitted to be given by either party hereunder, shall be deemed sufficiently given, if mailed by certified mail, return receipt requested, and addressed to the party to whom notice is given as follows:

If to LIMR:

J. Todd Abrams, Ph.D. Director of Philanthropy and Business Development
Lankenau Institute for Medical Research
100 E. Lancaster Avenue
Wynnewood, PA 19096

With a Copy to:

Office of the General Counsel
Main Line Health
Bryn Mawr Hospital Legal Department, 1st floor, D Wing

130 So. Bryn Mawr Avenue
Bryn Mawr, PA 19010
Attention: Senior Vice President and General Counsel

If to NewLink:

Dr. Nick Vahanian
Chief Medical and Operations Officer
2901 South Loop Drive
Suite 3900
Ames, Iowa 50010

24. Assignment. This Agreement shall inure to the benefit of and be binding on the parties' permitted assigns and successors in interest. Except as provided in this Section 24, neither party shall assign or transfer this Agreement without the express prior written consent of the other, such consent not to be unreasonably withheld. Notwithstanding the foregoing, an assignment of this Agreement by NewLink in connection with the transfer of all or substantially all of its assets or equity, or by reason of acquisition, merger, consolidation or operation of law shall not require LIMR's consent.

25. Entire Agreement. This Agreement, together with any exhibits attached hereto, represents the entire agreement between the parties with respect to the subject matter hereof, and may only be subsequently altered or modified by an instrument in writing. This Agreement cancels and supersedes any and all prior oral or written agreements between the parties that relate to the subject matter of this Agreement.

26. Mediation and Arbitration.

a. Except as otherwise expressly provided herein, both parties agree that they shall use good faith, reasonable efforts to attempt to resolve any dispute arising from this Agreement, or the breach thereof, through mediation before proceeding to arbitration proceedings as set forth below. Both parties agree that at least one employee (with respect to NewLink an authorized executive officer of NewLink) who is authorized and capable of negotiating an agreement on behalf of such party, shall, within three (3) weeks of receipt of written notification of a dispute, meet with at least one employee (an executive officer in the case of NewLink) of the other party who is also authorized and capable of negotiating an agreement on behalf of such party. If no agreement can be reached, both parties agree to meet again within a four (4) week period after the initial meeting to negotiate in good faith to resolve the dispute.

b. If no agreement can be reached after this second meeting or if otherwise expressly provided herein, both parties agree to submit the dispute to binding arbitration under the Commercial Arbitration Rules of the American Arbitration Association ("AAA") before a panel of three (3) independent arbitrators each having at least ten (10) years experience in the biomedical licensing area. The identity of the arbitrators shall be mutually agreed upon by the parties, provided, however, that if they are unable to agree on such arbitrators within ten (10) business days after the earlier of (i) the AAA providing them with a list of potential qualified arbitrators or (ii) the delivery of a list of at least ten potential qualified arbitrators by one party to the other party, then AAA shall select the arbitrators from the relevant list. Discovery shall be permitted as set forth in the Federal Rules of Civil Procedure with respect to the performance by the parties of their obligations under this Agreement and such other matters as the arbitrators may determine Judgment upon an award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

27. Waiver. A failure by one of the parties to this Agreement to assert its rights for or upon any breach or default of this Agreement shall not be deemed a waiver of such rights nor shall any such waiver be implied from acceptance of any payment. No such failure or waiver in writing by any one of the parties hereto with respect to any rights, shall extend to or affect any subsequent breach or impair any right consequent thereon.

28. Severability. The parties agree that it is the intention of neither party to violate any public policy, statutory or common laws, and governmental or supranational regulations; that if any sentence, paragraph, clause or combination of the same is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

29. Force Majeure. Neither party shall lose any rights under this Agreement or be liable to the other party for damages or losses on account of failure of performance by the defaulting party if the failure is occasioned by war, strike, fire, act of God, earthquake, flood, explosions, sabotage, strikes or labor disputes, lockout, riots, invasions, acts of war, embargo, governmental acts or orders or restrictions, disruptions of supplies of adequate raw materials, terrorist attacks, or any other reason where failure to perform is

beyond the reasonable control and not caused by the negligence or intentional conduct or misconduct of the nonperforming party, and such party has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a party be required to settle any labor dispute or disturbance.

30. Marking. NewLink agrees to mark the Licensed Products covered by the Patent Rights in the United States with all applicable U.S. Patent numbers. NewLink agrees to mark the Licensed Products covered by the Patent Rights in other countries with all applicable patent numbers issued by such other countries to the extent required by applicable laws in order to preserve patent rights.

31. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not constitute a part hereof.

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IN WITNESS WHEREOF, the parties have signed this Agreement on and as of the Effective Date.

LANKENAU INSTITUTE FOR MEDICAL RESEARCH		**NEWLINK GENETICS CORPORATION**	
By:	/s/Edward Jones., Jr.	Name:	/s/ Nicholas N. Vahanian
Title:	Chairman	Title:	Chief Operations Officer
Date:	12/11/07	Date:	12/21/07

Exhibit A

Patent Rights

"Indoleamine 2,3 Dioxygenase-2", **[*]**

Exhibit B

CRADA

NewLink Genetics Corporation will provide financial support to fund research at Lankenau Institute for Medical Research (LIMR) for one year ("Initial Year") with an option for future one-year renewals based on need and progress. The Initial Year shall begin on October 1, 2007 and end on May 31, 2008. All subsequent years for purposes of these financial support obligations shall begin on June 1 of the applicable year and end on May 31 of the following calendar year. The support funds will be committed towards personnel and consumable expenses that are directly related to this research project.

Project Scope: The first part of the project will involve study/ analysis of IDO-2 enzyme and biological pathways related to this enzyme. The second part of this project involves synthesis and evaluation of inhibitory compounds/molecules for IDO through an established collaboration of LIMR with William Malachowski and his colleagues in the Department of Chemistry at Bryn Mawr College. Further aim of this project is to evaluate 'hits' that may emerge from screening of the NCI compound collection being conducted at NCI Frederick under the auspices of a RAND award, from compound collections planned for screening elsewhere this fall, or from other investigators through MTA's as appropriate, during the term of this proposal.

Research Aims: Are as summarized below

Scientific Milestones proven by:

[*]

Year 1 Budget: Support for **[*]** personnel, **[*]** is included in this project. Supply costs will be estimated at **[*]** annually.

Scientific Personnel Costs	**[*]**
[*]	
Supply costs	**[*]**
Total Potential Project Reward	**[*]**

The amounts set forth above for Year 1 shall be paid within sixty (60) days after the execution and delivery of this Agreement.

Any amounts due with respect to CRADA funding for Year 2 and years subsequent to that shall be paid quarterly in advance.

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (the "Agreement") is made and entered into by and between **LANKENAU INSTITUTE FOR MEDICAL RESEARCH** ("LIMR") and **NEWLINK GENETICS CORPORATION** ("NewLink") for the licensing of certain intellectual property rights to NewLink, effective on this 23 day of April, 2009 (the "Effective Date").

WHEREAS, LIMR owns certain technology and intellectual property rights developed by Dr. George Prendergast at LIMR relating to **[*]** inhibitors of Indoleamine 2, 3 Dioxygenase ("IDO"), and

WHEREAS, LIMR filed U.S. provisional patent application no. **[*]** covering such IDO inhibitors and related inventions as of **[*]**; and

WHEREAS, NewLink and LIMR have conducted further collaborative research on such IDO inhibitors and intend to **[*]**; and

WHEREAS, NewLink would like to obtain the exclusive, worldwide license rights from LIMR, , **[*]** and LIMR desires to grant such rights to NewLink, under LIMR's interest in such technology and intellectual property, and in any improvements or derivatives thereof developed by LIMR or jointly by LIMR and NewLink, for the purpose of developing the technology into marketable therapeutic or diagnostic products.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Definitions.

a. Affiliate(s). "Affiliate" means, with respect to NewLink, any individual, company or other business entity, in whatever country organized, that directly or indirectly controls, is controlled by, or is under common control with NewLink. For purposes of this Agreement, the term "control" (with correlative meanings for the terms "controlled by" and "under common with") shall mean that the applicable individual, company or entity owns, directly or indirectly, more than thirty-three percent (33%) of the voting stock or equity of NewLink, or otherwise has the ability to direct and manage the business affairs of NewLink (whether through contract or otherwise).

b. Consideration. Subject to the other provisions of this Agreement, "Consideration" shall mean any and all revenues or payments in-kind received by NewLink or its Affiliates from a Sublicensee (as defined in Article 3) as consideration for the grant by NewLink of a sublicense under the rights granted to NewLink by LIMR pursuant to Article 2(a) hereof, *but excluding* sums or amounts received: (i) for the purchase of an equity interest in NewLink (which for purposes of this Agreement shall be valued at fair market value at the time of receipt by NewLink); (ii) as fair market value payments or reimbursements for

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research and development work performed by or on behalf of NewLink (which reimbursement may be in the form of reasonable and typical FTE rates); (iii) for purchase or supply of Licensed Product; and (iv) as a loan, or as reimbursement of patent prosecution costs, or as payment of a share of amounts recovered in enforcing a patent or other intellectual property rights. Furthermore, if NewLink or an Affiliate receives from a Sublicensee payments or revenue or other consideration, and such payments or revenue or other consideration is in consideration both for the grant of a sublicense under the Licenses granted to NewLink hereunder as well as for the grant of a license or sublicense to other technology controlled by NewLink but not acquired from LIMR under this Agreement, then the "Consideration," for purposes of this Agreement, shall be deemed to be such payments or revenue or other consideration multiplied by a percentage that fairly represents, as reasonably determined and mutually agreed upon by the parties, the percentage contribution of the LIMR Technology and the Patent Rights to the total value of the rights licenses or sublicensed by NewLink or its Affiliate to such Sublicensee. Either party may request an independent third party fair market value determination of such reasonable percentage and in such a case the parties shall equally share the cost of obtaining such determination.

c. **[*]** Claim. "**[*]** Claim" shall mean a claim in **[*]** as filed with the United States Patent and Trademark Office on **[*]**.

d. Improvements. "Improvement" shall mean any improvement, modification, derivative, and/or enhancement of the LIMR Technology or the Patent Rights developed, acquired or otherwise controlled by LIMR at any time after the Effective Date.

e. Licensed Product. "Licensed Product" shall mean any article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered or claimed by a Valid Claim within the Patent Rights. For clarity, a "Licensed Product" shall not include other product or material that (a) is used in combination with Licensed Product, and (b) does not constitute an article, composition, apparatus, substance, chemical material, method, process or service whose manufacture, use, or sale is covered or claimed by a Valid Claim within the Patent Rights.

f. LIMR Technology. "LIMR Technology" shall mean the technology and/or know-how owned or controlled by LIMR that specifically relates to the subject matter of the Patent Rights or is otherwise necessary or useful for the practice of the Patent Rights.

g. Net Sales. "Net Sales" shall mean the gross consideration actually received or collected by NewLink and/or any Affiliate from the transfer, sale or other commercial distribution of any Licensed Product to a third party customer, less:

(1) revenue credited or rebated on returns and allowances, and bad debts;

(2) discounts, in amounts customary in the trade and to the extent actually granted, for quantity purchases, for prompt payments and for wholesalers and distributors;

(3) transportation, shipping, insurance and delivery charges or allowances;

(4) customs, duties;

(5) sales, use, excise, value-added and other taxes (other than the taxes on the income of the selling party or NewLink) or other governmental charges measured by sales;

(6) governmental and managed care rebates or chargebacks to the extent actually incurred or allowed with respect to Licensed Product sold during the relevant time period to group purchasing organizations, hospitals, or other buying groups; and

(7) retroactive price reductions that are actually allowed or granted.

Sales between or among NewLink and its Affiliates will be excluded from the computation of Net Sales, but the subsequent final sales of such Licensed Product to third parties by NewLink or its Affiliates will be included in the computation of Net Sales. In addition, transfers or dispositions of Licensed Products in commercially reasonable quantities for nominal consideration the use of which is restricted to either charitable, sampling or promotional purposes or for preclinical, clinical, manufacturing (without sale), scale-up, regulatory or governmental purposes shall not be considered a "sale" or "other commercial disposition" and shall not be included for purposes of calculating Net Sales under this Agreement.

If NewLink (or its Affiliate) sells a Licensed Product in combination with another active component or ingredient, which is not itself a Licensed Product (a **"Combination Product"**), for one selling price, then the "Net Sales of such Combination Product, for the purpose of determining the royalty owed, shall be the Net Sales resulting from such sale, as set forth above, multiplied by a factor that reflects the fair market value, in such Combination Product, of the Licensed Product therein, compared to the total market value of the Combination Product including its other active components or ingredients, such factor to be determined reasonably and in good faith by NewLink and LIMR.

h. Patent Rights. "Patent Rights" shall mean (a) the patent applications identified on **Exhibit A** of this Agreement; (b) all patents and patent applications of LIMR covering or claiming any improvement, modification, derivative, and or enhancement of the LIMR Technology or of any of the patent applications or rights or foreign counterparts described in subclauses (a), (c), (d) or (e) of this definition; (c) all continuing patent applications (including divisional, substitution, continuations and continuations-in-part) based on any of the foregoing applications; (d) all rights and interest held, acquired or otherwise

controlled by LIMR in and to any patents issuing on any of the foregoing applications (including any reexaminations, reissues, renewals, inventors certifications, and extensions thereof); and (e) all foreign counterparts worldwide of any such patent applications and patents.

i. Successful Completion. "Successful Completion" of a particular clinical trial means that such trial has been completed on sufficient numbers of subjects to meet the regulatory requirements for proceeding to the next phase of clinical trials, the final report analyzing the data from such subjects in such trial has been completed, and the results of such data support initiating the next phase of clinical trials on the drug studied in such trial.

j. Valid Claim. A "Valid Claim" means (i) a claim of an issued patent in the Patent Rights that (a) has not expired or been abandoned; (b) has not been disclaimed; (c) has not been canceled or superseded, or if cancelled or superseded, has not been reasserted; (d) has not been revoked, held invalid or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such claim in any country in which such patent may have issued (from which no further appeal has or may be taken); and/or (e) abandoned in accordance with or as permitted by the terms of this Agreement or by mutual written consent; or (ii) a claim included in a pending patent application under the Patent Rights, which claim is being actively prosecuted in accordance with this Agreement, has been subject to prosecution for protection for no more than five (5) years and has not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority in such country (and from which no appeal is or can be taken), and/or abandoned in accordance in accordance with or as permitted by the terms of this Agreement by mutual written consent.

2. Exclusive License.

a. License Grant. Subject to the retained rights of LIMR and the government set forth in subsection 2(b) below, LIMR hereby grants to NewLink the exclusive, world-wide, royalty-bearing license, with the right to grant sublicenses, under LIMR's interest in the LIMR Technology and the Patent Rights, to use and practice the LIMR Technology and the Patent Rights in all fields and to make, have made, use, sell, offer for sale, and/or import Licensed Product in all fields (the "License").

With respect to any Licensed Products covered by Patent Rights that have been discovered using Federal funding, NewLink and its sublicensees shall comply (to the extent applicable) with the requirements of the Bayh-Dole Act which require that "any products embodying the invention or produced through the use of the subject invention will be manufactured substantially in the United States," (United States Code, Title 35, Part II, Chapter 18, Section 204), *except* if there is an exception to such requirement, and provided that LIMR shall use

reasonable efforts, if reasonably requested by NewLink, to request and obtain an exception to such requirement.

b. Retained Rights. Notwithstanding the foregoing, LIMR expressly reserves a non-exclusive, non-transferable, royalty-free right to use the Patent Rights and the LIMR Technology, including use by its staff and researchers and affiliates for its internal non-commercial, educational and research purposes only, including without limitation the right of LIMR to publish its research, subject to the reasonable prior review by NewLink to the extent such publication would disclose confidential LIMR Technology licensed hereunder. LIMR shall temporarily refrain from publication for a reasonable period of time to accommodate any patent filings or other regulatory actions intended to protect any confidential LIMR Technology licensed hereunder, such period of time not to exceed the later of one year from (x) the date on which such confidential LIMR Technology was created, developed, discovered, conceived and/or reduced to practice or (y) the date on which such confidential LIMR Technology was licensed to NewLink hereunder. Further, the licenses granted to NewLink in Section 2(a) are subject to certain rights reserved by the United States government pursuant to applicable law or regulation in any inventions in the Patent Rights made with federal funding pursuant to RO1CA109542.

3. Sublicenses. NewLink and its Affiliates shall have the right to grant sublicenses to third parties (each, a "Sublicensee") under the LIMR Technology and Patent Rights (with the right to further sublicense) for all purposes including to research, develop, make, have made, use, sell, offer for sale, and import the Licensed Products. Such sublicenses shall be in writing and expressly subject to the terms of this Agreement, and shall not grant rights under the Patent Rights that exceed the scope of the rights expressly granted under this Agreement. Any such sublicense agreement that is materially inconsistent with this Agreement shall constitute a material breach of this Agreement by Company. NewLink agrees to require that its Sublicensees must not violate the terms of this Agreement, and that such Sublicensees shall do the same with respect to any further subsublicenses, and NewLink shall use commercially reasonable efforts to enforce such obligations for the benefit of LIMR. At LIMR's request, NewLink will provide LIMR with a copy of each sublicense and subsublicense in order to allow LIMR to review such sublicenses and subsublicenses to assure consistency with this Agreement (which copy may be redacted to delete any confidential information that does not relate to the Patent Rights or LIMR Technology or the royalties, revenue or consideration thereunder or the sublicense of rights thereunder). If LIMR performs such a review on any sublicense or subsublicense agreement, those agreements reviewed by LIMR, not including any subsequent amendments or changes to the agreements, shall be deemed to conform to this Agreement unless LIMR has raised an objection to one or more of such sublicense or subsublicense agreements. If LIMR has requested copies of the Agreement, New Link shall automatically provide copies of any amendments in existence at the time of the request and subsequently at the time such amendments are entered into. Upon termination of this Agreement in compliance with the notice and other provisions of this Agreement, and subject to Section 4(e) below, any such sublicenses between NewLink and its

sublicensees will remain in effect and be assigned directly to LIMR, which shall have the right to cancel any such sublicense if such sublicensee is not then in compliance with the terms of its sublicense and the applicable terms of this Agreement. Notwithstanding the foregoing, LIMR shall not be responsible for any obligation of NewLink under any such agreement which obligation accrued prior to the date of such assignment and if there is any such unperformed obligation which is ongoing or which affects the obligations of the subsublicensee or its ability to perform, LIMR may elect to cancel such sublicense agreement, without liability, upon written notice to such subsublicensee. Upon such a cancellation, the subsublicensee may sell all Licensed Products in its inventory and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided it is not in default under its subsublicense agreement and further provided it pays to LIMR all payments required to be paid to the sublicensor thereunder and provides one or more accountings of all such sales to LIMR (1) within thirty (30) days of LIMR's request therefore and (ii) within thirty (30) days after the last such sale, such accountings to be certified as true, complete and correct by such sublicensee's chief financial officer.

4. Term and Termination. The term of this Agreement shall commence as of the Effective Date and shall stay in effect until the last to expire issued Valid Claim covering Licensed Products included in the Patent Rights, unless otherwise terminated earlier as provided below in this Article 4 (collectively, the "Term").

a. If LIMR believes in good faith that NewLink has materially breached its obligations under Section 9(a), then LIMR shall, in accordance with the terms of this paragraph 4, have the right and option to reduce NewLink's exclusive License to a nonexclusive license or revoke the License in its entirety (by terminating the Agreement), provided that prior to taking this action:

(1) LIMR shall provide NewLink written notice of the perceived breach, describing in detail the basis for LIMR's belief that such perceived breach has occurred, describing the preferred method of cure and the proposed action to be taken by LIMR in the event of non-cure; and

(2) NewLink shall have ninety (90) days to establish that it has met or will, within such ninety (90) day period, meet the applicable obligations; if the parties are still in dispute as to whether NewLink has met such obligations or cured such breach within ninety (90) days after receipt of notice from LIMR, the dispute will be submitted to binding arbitration in accordance with Section 23(b) of this Agreement, and if such arbitration determines that NewLink materially breached its obligations under Section 9(a) and did not cure such breach, then LIMR shall have the option to terminate this Agreement or to convert the License granted to NewLink in Section 2(a) to a non-exclusive license, in each case, upon prior written notice to NewLink.

b. LIMR may terminate this Agreement immediately by providing NewLink written notice of termination, if:

(1) NewLink ceases to function as a going concern;

(2) a bankruptcy petition or action is filed or taken by or against NewLink under any United States bankruptcy law;

(3) a receiver, assignee or other liquidating officer is appointed with control for all or substantially all of the assets of NewLink; or

(4) NewLink makes an assignment for the benefit of creditors of all or substantially all its assets;

provided, that, in the case of subclauses (b)(2), (3) or (4) above, such aforementioned circumstance is not remedied, dismissed or stayed within the earlier of sixty (60) days of (x) occurrence of (b)(2), (3) or (4) or (y) LIMR's notice of its intent to terminate this Agreement;

Notwithstanding anything in Sections 4(a) or (b) or 23 to the contrary, at any time that LIMR or NewLink believes that the other party has defaulted under this Agreement and that such default will irreparably harm such party, in addition to its rights under this Agreement and at law, such party shall have the right to seek all applicable equitable remedies.

c. If NewLink fails to make any payment whatsoever due and payable to LIMR hereunder, LIMR shall have the right to terminate this Agreement effective on ninety (90) days written notice, unless NewLink shall make all such payments to LIMR within said ninety (90) day period, and provided that the payments demanded by LIMR are not disputed by NewLink. In the event of a dispute of such payments by NewLink, the parties shall use good faith efforts to resolve the dispute, which if not resolved by the end of four (4) months either party may submit the dispute to binding arbitration pursuant to Section 23(b). Any disputed payments submitted to arbitration hereunder be paid into escrow the arbitrator or other independent escrow agent acceptable to both parties in their reasonable discretion unless and until determined due by the arbitrator under Section 23(b), provided, however that if the arbitrator determines that amounts are payable by NewLink to LIMR, then such outstanding amounts will bear interest back to the date that they originally accrued at the default rate of Prime plus 4%. Prime shall be the prime rate published by the Wall Street Journal or if the Wall Street Journal publishes more than one prime rate, then the average of the prime rates published by the Wall Street Journal, and if the Wall Street Journal does not publish a prime rate, then the prime rate of the largest bank in Philadelphia, Pennsylvania.

d. NewLink shall have the right to terminate this Agreement at any time on ninety (90) days prior written notice to LIMR, provided that NewLink shall remain obligated to complete payment of all amounts that have accrued and are owed to LIMR through the effective date of the termination. In the event NewLink terminates the Agreement, the license granted hereunder shall be deemed terminated, and all rights with respect to the subject matter thereof revert to LIMR

and all further obligations of NewLink to LIMR (except for obligations accrued prior to such termination) shall automatically be terminated.

e. Upon expiration or termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that has accrued prior to the effective date of such termination. NewLink and any Sublicensee thereof may, however, after the effective date of such termination, sell all then existing Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that NewLink shall make the payments to LIMR as required by Articles 8 & 9 of this Agreement and shall submit the reports as required by Article 11 hereof.

f. Sections 4(e), 4(f), 7(b) (but solely with respect to sales made pursuant to Section 4(e)), 11, 12, 13 (solely for the period specified therein), 14, 18, 19, 20, 21 and 23 shall survive termination or expiration of this Agreement.

5. Ownership. LIMR represents and warrants to NewLink that LIMR owns the rights to the LIMR Technology and the Patent Rights (except to the extent any such LIMR Technology and Patent Rights are co-owned by NewLink) and has the right to license its interest in the LIMR Technology and the Patent Rights to NewLink, subject to the rights retained by the United States government and LIMR as described in Section 2(b).

6. Patent Prosecution. Commencing on the Effective Date, NewLink shall have the right and responsibility, at its expense and in its reasonable discretion, for the preparation, filing, prosecution and maintenance of any patent applications and patents included in the Patent Rights, in consultation with LIMR. NewLink shall provide LIMR the opportunity to review and comment upon such patent applications prior to filing, and on all communications with patent offices in all applicable countries and jurisdictions, the selection of countries for filing of patent applications, responses to office actions, and other substantive patent documents prior to filing and the right to have such documents revised prior to filing to reflect such comments. Promptly after the Effective Date, LIMR will transfer to NewLink (or its selected counsel) all patent prosecution files for the Patent Rights, shall provide to NewLink such executed documents or instruments as needed for NewLink to undertake such prosecution efforts, and shall provide NewLink all reasonable assistance in such prosecution. NewLink shall reimburse LIMR for the reasonable out-of-pocket costs, based on detailed invoices of such costs, actually incurred in conducting such prosecution and maintenance of the Patent Rights prior to the Effective Date; provided that LIMR has provided NewLink with an invoice for such costs together with appropriate documentation outlining the costs incurred. LIMR shall provide NewLink with all information necessary or useful for NewLink's filing and prosecution of such Patent Rights and shall cooperate fully with NewLink so as to maximize NewLink's rights. NewLink shall not abandon or opt not to file any patent or patent application included in the Patent Rights without the prior notice to LIMR. NewLink may elect in writing to cease the continued prosecution or maintenance of particular Patent Right in a country, and on such notice NewLink shall no longer have any further rights or responsibility for such prosecution or maintenance, or obligation to pay any amounts therefore, or any further rights under such specific Patent Right in such

country, and LIMR may in its discretion continue such prosecution. Any such notice shall be given by NewLink to LIMR in sufficient time to enable LIMR an adequate time period to protect its rights, but in no case less than three (3) months prior the filing deadline imposed or promulgated by any governing or regulatory authority for filing any such protective document.

7. Royalties; Sublicense Payments.

a. NewLink shall pay the following royalties to LIMR during the Term on a country-by-country and Licensed Product-by-Licensed Product basis, subject to Section 7(b) below:

(1) For Licensed Product covered or claimed by a **[*]** Claim: **[*]** of the Net Sales of such Licensed Product in countries where the Licensed Product is covered by a Valid Claim at the time of sale.

(2) For Licensed Product not covered by a **[*]** Claim: **[*]** of the Net Sales of such Licensed Product in countries where the Licensed Product is covered by a Valid Claim at the time of sale.

b. In the event: (i) one or more additional technologies (including any patents related thereto) must be licensed (e.g. formulation, cross linking) by NewLink, its Affiliates, and/or Sublicensees from any third party to develop, make, use, import, sell, offer for sale, or import a Licensed Product in any country, or (ii) royalties are payable on the sale of a Licensed Product (as defined hereunder) pursuant to the Exclusive License Agreement between LIMR and NewLink, dated December 21, 2007, or pursuant to the License Agreement between LIMR and NewLink, dated July 7, 2005, (the "Prior Agreements"), NewLink shall be entitled to fully offset against royalties otherwise due to LIMR hereunder an amount equal to the aggregate royalties owed to such third party and owed to LIMR under the Prior Agreements; provided, however, that in no event shall NewLink pay LIMR a royalty hereunder of less than **[*]** of Net Sales.

c. If NewLink grants a sublicense, under the License rights granted under this Agreement to NewLink, to a Sublicensee pursuant to Article 3 hereof, NewLink shall pay LIMR **[*]** of any Consideration received by NewLink from such Sublicensee, for each such sublicense during the Term. For clarity, sales of Licensed Product by a Sublicensee shall not be included in Net Sales.

d. No more than one royalty payment shall be due with respect to a sale of a particular Licensed Product. No multiple royalties shall be payable because any Licensed Product, or its manufacture, sale or use is covered by more than one Valid Claim in a given country.

8. Payment of Royalties. Royalties and sublicense payments shall be payable by NewLink quarterly in U.S. dollars within forty-five (45) days of the end of the calendar quarter. NewLink shall render quarterly reports to LIMR on or before the last day of April, July,

October, and January, as applicable, showing the amount of Net Sales received by NewLink during the most recently concluded fiscal quarter and the appropriate royalties and sublicense payments due to LIMR certified by NewLink's chief financial officer (or comparable financial officer) as true, correct and complete. Each such report shall be accompanied by payment of the royalties and/or sublicense payments due for such fiscal quarter. After the first commercial sale of any Licensed Product pursuant to this Agreement, and upon LIMR's request and at its expense, NewLink shall provide LIMR with copies of NewLink's then-existing standard audited financial statements covering the royalties and sublicense payments due under this Agreement within thirty (30) days of LIMR's request. NewLink shall pay estimated royalties payments quarterly with an annual reconciliation and of all payments performed within thirty (30) days of receipt of audited numbers. For the purpose of determining royalties payable under this Agreement, any Consideration NewLink receives from Sublicensees in currencies other than U.S. dollars and any Net Sales denominated in currencies other than U.S. dollars shall be converted into U.S. dollars at the same conversion rate that NewLink actually receives on such conversion at the time of the transaction in question which gave rise the Consideration.

9. Diligence; Milestones and Associated Payments.

a. Diligence. NewLink has represented to LIMR, to induce LIMR to issue this exclusive license, that it will commit itself to a diligent program of developing and exploiting **[*]** so that public utilization will result there from. As part of the consideration for the exclusive license granted to NewLink hereunder, NewLink has agreed to use commercially reasonable efforts to develop and exploit **[*]**. Notwithstanding the foregoing, NewLink will not be deemed in breach of this Section 9(a) as long as it is using commercially reasonable efforts to develop and exploit **[*]** as defined under one or both of the Prior Agreements.

It is understood and agreed by the parties that the actions by any Affiliate or Sublicensee may satisfy the above obligations.

b. Milestone Payments to LIMR. Subject to Section 9(c) below, NewLink will pay to LIMR:

(1) **[*]** for the **[*]** for a Licensed Product in **[*]**;

(2) **[*]** for the **[*]** on a Licensed Product;

(3) **[*]** for the **[*]** on a Licensed Product;

(4) **[*]** for the **[*]** on a Licensed Product;

(5) **[*]** for the **[*]** for a Licensed Product in **[*]**;

(6) **[*]** for **[*]** for a Licensed Product **[*]** in **[*]**.

For clarity, each such milestone payment above shall be payable only once under this Agreement.

c. In the event: (i) one or more additional technologies (including any patents related thereto) must be licensed (e.g. formulation, cross linking) by NewLink, its Affiliates, and/or Sublicensees from any third party to develop, make, use, import, sell, offer for sale, or import a Licensed Product in any country, or (ii) milestone payments are payable pursuant to the Prior Agreements in connection with **[*]**, NewLink shall be entitled to fully offset against a milestone payment payable upon the occurrence of a milestone event under Section 9(b)(5) or 9(b)(6) above with respect to a Licensed Product, an amount equal to the aggregate amount of any milestone payments owed to such third party or owed to LIMR under the Prior Agreements upon the occurrence of such milestone event with respect to such Licensed Product; provided, however, that in no event shall the amount payable under Section 9(b)(5) or 9(b)(6), as applicable, be less than **[*]**.

10. Reports and Accounting. NewLink shall provide to LIMR no less than once a year during the Term a written report regarding NewLink's product development, royalty and sublicense payment (i.e., receipt of Consideration) information with respect to Licensed Products and milestone status.

The report shall be certified by an officer of NewLink as true, correct and complete. This report is in addition to the reports required under Section 8 hereof.

11. Indemnity. NewLink shall defend and indemnify and hold LIMR, its parent corporations, affiliates, trustees, officers, agents and employees (the "Indemnitees") harmless from any judgments and other liabilities based upon claims or causes of action brought by a third party against any Indemnitee which arise out of **[*]** by NewLink, its Affiliates or any Sublicensees, or from **[*]** by the end users of Licensed Products or from **[*]** by NewLink, its Affiliates or any Sublicensees of **[*]**, except to the extent that **[*]**, provided that LIMR promptly notifies NewLink of any such claim coming to its attention and that it cooperates with NewLink in the defense of such claim. If any such claims or causes of action are made, NewLink counsel, the identity of whom LIMR does not have a reasonable objection, shall defend LIMR. If LIMR has a reasonable objection to the counsel selected by NewLink, LIMR and NewLink shall cooperate with each other reasonably and in good faith so that NewLink can engage legal counsel to whom LIMR does not have reasonable objection. LIMR reserves the right to be represented by its own counsel at its own expense. NewLink shall not settle any claim that requires the payment of money or the cessation of research and development in each case by LIMR without the prior written consent of LIMR in its sole discretion.

12. Limitations of Liability. EXCEPT FOR THE INDEMNIFICATION OBLIGATIONS ABOVE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING LOST REVENUES OR LOST PROFITS, WHETHER BASED ON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT OR OTHERWISE ARISING OUT OF THIS AGREEMENT, AND REGARDLESS OF WHETHER SUCH PARTY

HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING ANYTHING TO THE CONTRARY SET FORTH HEREIN, NEWLINK'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL BE LIMITED TO **[*]**

13. Insurance. At such time as NewLink, its Affiliates, or Sublicensees, initiates or otherwise enters into clinical trials of any Licensed Product or commercially distributes or sells Licensed Products (other than for the purpose of obtaining regulatory approvals), NewLink shall at its sole cost and expense, procure and maintain comprehensive general liability insurance in amounts not less than $3,000,000 per incident and naming the Indemnitees (defined in Section 11 above) as additional insureds. LIMR may require such minimum requirements to be increased from time to time if the minimum amounts of such insurance carried by prudent companies in the general size of NewLink and in similar industries as NewLink is higher, so that NewLink will at all times carry commercially reasonable amounts of insurance. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) broad form contractual liability coverage for NewLink's indemnification under this Agreement. If NewLink elects to self-insure all or part of the limits described above (including deductibles or retentions, which are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to LIMR and Main Line Health Vice President Insurance and Main Line Health, Inc's chief financial officer in each of their sole and absolute discretions. Such insurance will be considered primary as to any other valid and collectible insurance, but only as to acts of the named insured. The minimum amounts of insurance coverage required shall not be construed to create a limit of NewLink's liability with respect to its indemnification and other obligations under this Agreement. NewLink shall provide LIMR with written evidence of such insurance promptly upon written request of LIMR. NewLink shall use provide LIMR with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance. If NewLink does not obtain replacement insurance providing comparable coverage immediately, LIMR shall have the right to terminate this Agreement effective immediately without notice or any additional waiting periods. NewLink shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any Licensed Product is being clinically tested, commercially distributed or sold by NewLink (or an agent on its behalf) or by a Sublicensee, Affiliate and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than five (5) years.

14. Mutual Confidentiality. NewLink and LIMR realize that certain confidential or proprietary information disclosed by one party (the "disclosing party") to the other party (the "receiving party") pursuant to this Agreement ("Confidential Information" of the disclosing party) shall be treated as confidential. For purposes of this Agreement, the term "Confidential Information" of a party means any of the following:

a. All information concerning the business or affairs of either party or its affiliates, including without limitation, all information relating to the LIMR Technology or to NewLink technology, the Patent Rights, the Licensed Product, and/or any and

all existing and potential research parameters, program requirements, strategies, products, technology, know-how, information, data, processes, systems, inventions, developments, formulations, applications, and methods of rendition of services relating to any of the foregoing;

b. All information received from third parties and held in confidence by either party or its affiliates, or

c. All information pertaining to the proposed business relationship(s) and/or transactions(s) between the parties, including without limitation, the terms thereof.

The Confidential Information of the disclosing party shall not be disclosed by the receiving party to any third party and shall not be used by the receiving party for purposes other than those contemplated by this Agreement without the prior written consent of the disclosing party. Any Confidential Information exchanged by the parties under this Agreement shall remain subject to such confidentiality and non-use obligations for a period of five (5) years from the termination or expiration of the Agreement. The confidentiality and non-use obligations under this Article 14 shall not apply to any information that:

a. Is or which later becomes publicly known through no fault of the receiving party, or

b. Is already in the receiving party's possession prior to the disclosure by the disclosing party to the receiving party as indicated in the receiving party's competent written records, or

c. Is subsequently disclosed to the receiving party, by a third party not under any obligation of confidentiality to the disclosing party, or

d. Is independently developed by the receiving party without use of the Confidential Information of disclosing party or any other information from the disclosing party that is protected by any other confidentiality obligations.

In addition, the receiving party may disclose specific Confidential Information of the other party to the extent such disclosure is required to be disclosed by court order or governmental law, rule or regulation, provided that the receiving party first gives the disclosing party prompt written notice of any such requirement and cooperates with the disclosing party in attempting to limit or seek confidential treatment with respect to such disclosure of such Confidential Information.

The provisions of this Section 14 are subject to the publication rights of LIMR as described in Section 2(b) hereof.

15. Disclaimer. Except as expressly set forth in Section 5 hereof, nothing contained in this Agreement shall be construed as:

a. a warranty or representation by LIMR as to the validity or scope of any Patent Rights; or

b. a warranty or representation that any Licensed Products manufactured, used or sold will be free from infringement of patents, copyrights, or third parties; except that LIMR represents that it has no knowledge of any existing issued patents or copyrights which might be infringed.

LIMR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO THE MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF LICENSED PRODUCTS.

16. Third Party Infringement.

a. Each party shall promptly notify the other party in writing of any alleged or actual infringement of the Patent Rights of which it becomes aware and which may adversely impact the rights of either party hereunder.

b. NewLink shall have the first right but not the obligation, at its expense, to bring an appropriate action against any person or entity directly or contributorily infringing the Patent Rights. LIMR shall cooperate reasonably with NewLink in such action, including by consenting to be named as a party to such action and furnishing a power of attorney upon request. Except as otherwise set forth in this Agreement, NewLink shall have sole control of the action brought by it; provided, however, that LIMR shall have the right to participate in such action against a third party infringer through counsel of its own choice and at its own expense.

c. In the event NewLink institutes legal action against an infringer hereunder, LIMR shall fully cooperate with and supply all assistance reasonably requested by NewLink, including, without limitation, by using commercially reasonable efforts to have its employees testify and grant interviews when requested and to make available relevant records, papers, information, samples, specimens, and similar items upon request of NewLink. LIMR shall render such cooperation at its own cost and expense ("LIMR's Costs"). NewLink shall keep LIMR reasonably informed of the progress of such action, and LIMR shall be entitled to be represented by counsel in connection with such action at its own expense.

d. NewLink shall bear the costs of all reasonable and customary expenses for such action (including attorneys' fees and expert fees). Any amounts paid to NewLink by third parties as a result of such action (in satisfaction of a judgment or pursuant to a settlement recovery) shall first be applied to the payment of NewLink's out-of-pocket expenses (including attorneys' fees and expert fees), second to LIMR's Costs, third to LIMR's other out-of-pocket expenses in connection with the matter (including attorneys' fees and experts fees), and then the balance of any such amounts shall be included in NewLink's calculation of Net Sales, applied to the quarter in which such recovery is obtained. NewLink shall have the right to settle any claims, but provided that if such settlement materially negatively affects

LIMR's interests such settlement shall be only upon terms and conditions that are reasonably acceptable to LIMR, such reasonable acceptance to be confirmed by LIMR in writing prior to NewLink's agreement to such settlement.

e. If NewLink elects to abandon such an action other than pursuant to a settlement with the alleged infringer that is reasonably acceptable to LIMR, NewLink shall give timely notice to LIMR who, if it so desires, may continue the action; provided, however, that the sharing of expenses and any recovery in such suit shall be as agreed upon between the parties. Any such notice shall be given by NewLink to LIMR in sufficient advance of the expiration of the applicable statute of limitations to enable LIMR an adequate time period to protect its rights, but in no case less than twelve (12) months prior to the expiration of such statute of limitations.

17. Technical Assistance. Throughout the term of the Agreement, LIMR agrees to permit NewLink and its designees to consult with its employees and agents regarding the LIMR Technology or any Improvements made after the Effective Date relating to the Licensed Products, at such times and places as may be mutually agreed upon; provided that NewLink agrees to limit such consultation to five (5) employee-investigator hours per week and make suitable arrangements directly with LIMR employees and agents and to compensate for such consultation at LIMR's then-current rates as communicated to NewLink.

18. Name. NewLink shall not use and shall not permit to be used by any other person or entity the name or logo of LIMR nor any adaptation thereof, or the name of LIMR's employees, in any advertising, promotional or sales literature, or for any other purpose without prior written permission of LIMR, except as required by governmental authority or applicable law, and provided that the foregoing shall not prevent NewLink from disclosing to third parties the existence of this Agreement.

19. Governing Law. This Agreement shall be construed, governed, interpreted and enforced according to the laws of the Commonwealth of Pennsylvania without reference to principles of conflicts of laws.

20. Notices. Any notice or communication required or permitted to be given by either party hereunder, shall be deemed sufficiently given, (i) when mailed by certified mail, return receipt requested, and addressed as below to the party to whom notice is given or (ii) when transmitted by facsimile, email or other electronic means, provided that the sender receives confirmation of transmission, and sends a confirmation copy as provided in clause (1), addressed as below:

If to LIMR:

J. Todd Abrams, Ph.D.
Director of Philanthropy and Business Development
Lankenau Institute for Medical Research

100 E. Lancaster Avenue
Wynnewood, PA 19096

With a Copy to:

Office of the General Counsel
Main Line Health
Bryn Mawr Hospital Legal Department, 1st floor, D Wing
130 So. Bryn Mawr Avenue
Bryn Mawr, PA 19010
Attention: Senior Vice President and General Counsel

If to NewLink:

Dr. Nick Vahanian
Chief Medical and Operations Officer
2901 South Loop Drive
Suite 3900
Ames, Iowa 50010

21. Assignment. This Agreement shall inure to the benefit of and be binding on the parties' permitted assigns and successors in interest. Except as provided in this Section 21, neither party shall assign or transfer this Agreement without the express prior written consent of the other, such consent not to be unreasonably withheld. Notwithstanding the foregoing, an assignment of this Agreement by NewLink to an Affiliate or in connection with the transfer of all or substantially all of the business to which this Agreement relates, whether by acquisition, merger, consolidation, operation of law or other transaction, shall not require LIMR's consent.

22. Entire Agreement. This Agreement, together with any exhibits attached hereto, represents the entire agreement between the parties with respect to the subject matter hereof, and may only be subsequently altered or modified by an instrument in writing. This Agreement cancels and supersedes any and all prior oral or written agreements between the parties that relate to the subject matter of this Agreement.

23. Mediation and Arbitration.

a. Except as otherwise expressly provided herein, both parties agree that they shall use good faith, reasonable efforts to attempt to resolve any dispute arising from this Agreement, or the breach thereof, through mediation before proceeding to arbitration proceedings as set forth below. Both parties agree that at least one employee (with respect to NewLink, an authorized executive officer of NewLink) who is authorized and capable of negotiating an agreement on behalf of such party, shall, within three (3) weeks of receipt of written notification of a dispute, meet with at least one employee (an executive officer in the case of NewLink) of the other party who is also authorized and capable of negotiating an agreement on behalf of such party. If no agreement can be reached, both parties agree to meet

again within a four (4) week period after the initial meeting to negotiate in good faith to resolve the dispute.

b. If no agreement can be reached after this second meeting or if otherwise expressly provided herein, both parties agree to submit the dispute to binding arbitration under the Commercial Arbitration Rules of the American Arbitration Association ("AAA") before a panel of three (3) independent arbitrators each having at least ten (10) years experience in the biomedical licensing area. The identity of the arbitrators shall be mutually agreed upon by the parties, provided, however, that if they are unable to agree on such arbitrators within ten (10) business days after the earlier of (i) the AAA providing them with a list of potential qualified arbitrators or (ii) the delivery of a list of at least ten potential qualified arbitrators by one party to the other party, then AAA shall select the arbitrators from the relevant list. Discovery shall be permitted as set forth in the Federal Rules of Civil Procedure with respect to the performance by the parties of their obligations under this Agreement and such other matters as the arbitrators may determine. Judgment upon an award rendered by the arbitrator may be entered in any court having jurisdiction thereof.

24. Waiver. A failure by one of the parties to this Agreement to assert its rights for or upon any breach or default of this Agreement shall not be deemed a waiver of such rights nor shall any such waiver be implied from acceptance of any payment. No such failure or waiver in writing by any one of the parties hereto with respect to any rights, shall extend to or affect any subsequent breach or impair any right consequent thereon.

25. Severability. The parties agree that it is the intention of neither party to violate any public policy, statutory or common laws, and governmental or supranational regulations; that if any sentence, paragraph, clause or combination of the same is in violation of any applicable law or regulation, or is unenforceable or void for any reason whatsoever, such sentence, paragraph, clause or combinations of the same shall be inoperative and the remainder of the Agreement shall remain binding upon the parties.

26. Force Majeure. Neither party shall lose any rights under this Agreement or be liable to the other party for damages or losses on account of failure of performance by the defaulting party if the failure is occasioned by war, strike, fire, act of God, earthquake, flood, explosions, sabotage, strikes or labor disputes, lockout, riots, invasions, acts of war, embargo, governmental acts or orders or restrictions, disruptions of supplies of adequate raw materials, terrorist attacks, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence or intentional conduct or misconduct of the nonperforming party, and such party has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a party be required to settle any labor dispute or disturbance.

27. Marking. NewLink agrees to mark the Licensed Products covered by the Patent Rights in the United States with all applicable U.S. Patent numbers. NewLink agrees to mark the Licensed Products covered by the Patent Rights in other countries with all applicable

patent numbers issued by such other countries to the extent required by applicable laws in order to preserve Patent Rights.

28. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not constitute a part hereof.

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IN WITNESS WHEREOF, the parties have signed this Agreement on and as of the Effective Date.

LANKENAU INSTITUTE FOR MEDICAL RESEARCH		**NEWLINK GENETICS CORPORATION**	
By:	/s/ George C. Prendergast, PhD	By:	/s/ Mario Mautino
	George C. Prendergast, PhD		
	Professor & President/CEO	Title:	VP of Drug Discovery & Intellectual Property
Date:	5/18/09	Date:	5/19/09

Exhibit A

Patent Rights

1. **[*]**

2. **[*]**

Exhibit 10.35

CONFIDENTIAL

LICENSE AGREEMENT

Between: THE UNIVERSITY OF BRITISH COLUMBIA

and

NEWLINK GENETICS CORPORATION

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Schedules

LICENSE AGREEMENT

BETWEEN:

THE UNIVERSITY OF BRITISH COLUMBIA, a corporation continued under the *University Act* of British Columbia with its administrative offices at 2075 Wesbrook Mall, Vancouver, British Columbia, V6T 1W5

("**UBC**")

AND:

NEWLINK GENETICS, a corporation incorporated under the laws of Iowa, with a registered office at 2901 S. Loop Dr., Suite 3900, Ames, IA 50010.

(the "**Licensee**")

WHEREAS:

UBC has been engaged in research during the course of which it has invented, developed and/or acquired certain technology relating to Indoleamine 2,3-Dioxygenase Inhibitors, which research was undertaken by Drs. Raymond Andersen, Grant Mauk, and Michel Roberge (the "**Investigators**") and co-workers in the UBC Departments of Biochemistry, Chemistry, and Earth and Ocean Sciences;

It is UBC's objective to exploit its technology for the public benefit, and to generate further research in a manner consistent with its status as a non-profit, tax exempt educational institution; and

The Licensee and UBC have agreed to enter into this license under which UBC grants Licensee the exclusive license rights under such technology and related intellectual property on the terms and conditions set out in this agreement (the "**Agreement**").

THE PARTIES AGREE AS FOLLOWS:

1.0 DEFINITIONS

1.1 In this Agreement:

(a) "**Affiliated Company**" or "**Affiliated Companies**" means, with respect to Licensee, another corporation or other business entity that controls, is controlled by, or is in common control with Licensee; where the term "control" means (with correlative meanings for the terms "controlled by" and "under common control with") that the applicable entity owns fifty percent (50%) or more of the voting shares of the subject entity, or otherwise has the ability to direct and manage the business affairs of such subject entity (whether through contract or otherwise);

(b) "**Annual Maintenance Fee**" is defined in Article 6.5;

(c) "**Annual Payment**" is defined in Article 6.1(d);

(d) "**Annual Report**" means a report in the form referred to in Article 12;

(e) "**Assigned Licensee Improvements**" means any new compounds made or discovered by Licensee or its Sublicensee(s) that are claimed or covered by the Patents in existence prior to the initial manufacture or discovery of such new compounds;

(f) "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by Licensee to accomplish a particular objective in the research, development or commercialization of a Product or Licensee Owned Improvement Product, such efforts as are substantially equivalent to those efforts and resources commonly used by Licensee for a comparable product, acting reasonably promptly and taking into account commercially relevant factors such as (as applicable) stage of development, product life, patent position, market potential and regulatory issues. Commercially Reasonable Efforts shall be determined on a market-by-market basis for any particular Product or Licensee Owned Improvement Product, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the Product or Licensee Owned Improvement Product and the market(s) involved;

(g) "**Confidential Information**" means all information, regardless of its form:

(i) disclosed by UBC to the Licensee, whether before or after the Effective Date, and which is identified in writing as "Confidential", which may include without limitation information and documents related to the Patents, Improvement Patents, Technology or any Improvements (including all derived analyses and conclusions); or

(ii) comprising the terms and conditions of this Agreement; or

(iii) disclosed by the Licensee to UBC and which is identified in writing as "Confidential",

except that "Confidential Information" does not include information:

(iv) possessed by the recipient (the "**Recipient**") prior to receipt from the disclosing party (the "**Discloser**"), other than through prior disclosure by the Discloser, as evidenced by the Recipient's business records;

(v) published or available to the general public otherwise than through a breach of this Agreement;

(vi) obtained by the Recipient from a third party with a valid right to disclose it, provided that the third party is not under a confidentiality obligation to the Discloser; or

(vii) independently developed by employees, agents or consultants of the Recipient who had no knowledge of or access to the Discloser's Confidential Information as evidenced by the Recipient's business records;

(h) "**Diagnostic Field of Use**"; means any use of:

(i) the Patents, Improvement Patents, Technology, or any Improvements, or

(ii) any compositions, formulations, Products or Licensee Owned Improvement Products containing or developed using the Patents, Improvement Patents, Technology or any Improvements,

for the diagnosis in humans of the presence of disease, for the prediction of the risk of disease or disease outcome, for the prediction of the response to therapy, or for guiding, developing and conducting a course of therapy;

(i) "**Dispute**" is defined in Article 11.5;

(j) "**Effective Date**" means February 1, 2007, the date on which this Agreement is effective.

(k) "**Effective Termination Date**" means the date on which this Agreement is terminated under Article 18;

(l) "**FDA**" means the United States Food and Drug Administration, (or any other equivalent regulatory authority outside the U.S.);

(m) "**First Use of the Technology**" means the earlier of either:

(i) the first use of the Licensed Patents, Technology or any Improvement, or

(ii) the first sale of a Product or Licensee Owned Improvement Product in exchange for valuable consideration;

(n) "**Human Clinical Trials**" means any Product or Licensee Owned Improvement Product testing involving human subjects;

(o) "**Improvements**" means collectively: (a) all UBC Improvements, (b) all Assigned Licensee Improvements; and (c) all Licensee Owned Improvements.

(p) "**Improvements Patents**" means any and all patents and patent applications (anywhere in the world) owned or controlled by UBC or the Licensee that claim or cover an Improvement;

(q) **"IND"** means an Investigational New Drug application in accordance with the rules and regulations of the FDA or foreign equivalents of such application;

(r) "**Indemnitees**" is defined in Article 9.1;

(s) "**Initial License Fee**" is defined in Article 3.5;

(t) "**Licensed Patents**" means collectively: (a) the Patents, and (b) all Improvements Patents that claim or cover UBC Improvements or Assigned Licensee Improvements;

(u) "**Licensee Owned Improvements**" means all improvements, variations, updates, modifications, and enhancements relating to the Patents or Technology made, discovered and/or acquired by the Licensee or any Sublicensee at any time after the Effective Date, which are based on or incorporate the Technology licensed under this Agreement, but excluding all Assigned Licensee Improvements. For clarity Licensee Owned Improvements includes any new

compounds made or discovered by Licensee or its Sublicensee(s) that: (i) are not claimed or covered by the Patents in existence prior to the initial manufacture or discovery of such new compounds, and (ii) are analogs of and synthesized based upon a compound, group of compounds, or pharmacophore that is claimed or covered by the Patents in existence prior to the initial manufacture or discovery of such new compounds;

(v) "**Licensee Owned Improvement Products**" is defined in Article 5.2(b);

(w) "**Mediator**" is defined in Article 11.6;

(x) "**Milestone Events**" is defined in Article 6.1(a);

(y) "**Milestone Payments**" is defined in Article 6.1(a);

(z) "**Net Revenue**" means all revenues, receipts, money, and the fair market value of any shares or other securities, or other consideration collected or received whether by way of cash, credit or other value received by the Licensee and/or any Sublicensee from the marketing, manufacturing, sale, distribution or other commercial disposition of Products or Licensee Owned Improvement Products to third party purchasers, less the following deductions to the extent actually accrued or allowed with respect to such sales:

(i) Trade, quantity and early payment discounts off of the invoice price;

(ii) amounts actually credited, rebated or allowed for rejections, returns or recalls of Products or Licensee Owned Improvement Products;

(iii) governmental and managed care rebates or chargebacks to the extent actually incurred or allowed with respect to Products or Licensee Owned Improvement Products sold during the relevant time period to group purchasing organizations, hospitals or other buying groups;

(iv) retroactive price reductions that are actually allowed or granted;

(v) sales, excise and other taxes (other than taxes on the income of the selling party), duties and government charges;

(vi) transportation, shipping and insurance to the extent separately reflected on the invoice; and

(vii) amounts written off as uncollectible bad debt after making all commercially reasonable efforts to collect such amounts.

Sales of Product and Licensee Owned Improvement Products between or among Licensee and its Affiliated Companies or Sublicensees will be excluded from the computation of Net Revenues, but the subsequent final sales of such Product or Licensee Owned Improvement Products to Third Parties by such parties will be included in the computation of Net Revenues. Further, transfers or dispositions of Products or Licensee Owned Improvement Products in commercially reasonable quantities for charitable, sampling or promotional purposes or for preclinical, clinical, manufacturing scale-up, regulatory or governmental purposes shall not be considered a "sale" and shall not be included for purposes of calculating Net Revenues;

(aa) "**New Technology**" means inhibitors of indoleamine 2,3-dioxygenase, or methods of inhibiting indoleamine 2,3-dioxygenase, disclosed by the Investigators to UBC at any time during the Term of this Agreement that:

(i) relate to the Patents or Technology in that they are directly competitive with, or may be used as a direct substitute for the Patents, Technology or any Improvement licensed under this Agreement; and

(ii) are not covered or claimed by the Patents and do not directly incorporate the Technology licensed under this Agreement;

For clarity, the term "New Technology" includes compounds identified by the Investigators that are inhibitors of indoleamine 2,3-dioxygenase where such compounds have different pharmacophores compared to the compounds claimed or covered by the Patents;

(bb) "**Objectionable Material**" is defined in Article 10.3;

(cc) "**Option**" is defined in Article 2.4;

(dd) "**Option Period**" is defined in Article 2.5;

(ee) "**Patents**" mean collectively: the U.S., Canadian and foreign patents and patent applications identified in Schedule "**A**", and including all rights in such patents and applications and to any and all inventions that are disclosed in any such patent or application, and all:

(i) counterparts, continuations, divisionals, continuing prosecution applications, and requests for continued examinations, extensions, term restorations, renewals, reissues, re-examinations, or substitutions of any such patent or applications;

(ii) corresponding international patent applications;

(iii) corresponding foreign patent applications, including supplementary protection certificates and other administrative protections; and

(iv) international and foreign counterpart patents resulting therefrom;

all of which will be deemed added, from time to time, to Schedule "**A**";

(ff) "**Payment Report**" means a report in the form referred to in Article 12 setting out in detail how the amount of Revenue was determined;

(gg) "**Phase I Clinical Trial**" means a Human Clinical Trial that would satisfy the requirements for a Phase 1 study as defined in U.S. FDA 21 C.F.R. 312.21(b) (or any U.S. successor legislation) or similar regulations in a country outside the U.S.;

(hh) "**Phase II Clinical Trial**" means a Human Clinical Trial that would satisfy the requirements for a Phase 2 study as defined in U.S. FDA 21 C.F.R. 312.21(b) (or any U.S. successor legislation) or similar regulations in a country outside the U.S.;

(ii) "**Phase Ill Clinical Trial**" means a Human Clinical Trial that would satisfy the requirements for a Phase 3 study as defined in U.S. FDA 21 C.F.R. 312.21(c) (or any U.S. successor legislation) or similar regulations in a country outside the U.S.;

(jj) "**Product**" means a product, good or service: (i) that is covered or claimed by, or the manufacture or use of which is covered or claimed by, a Valid Claim in a Patent or Licensed Patent; and/or (ii) that incorporates or is based upon any material aspect of the Technology and/or any Improvements other than a Licensee Owned Improvement;

(kk) "**Reagent Field of Use**" means any use of:

(i) the Patents, Improvement Patents, Technology or any Improvements, or

(ii) any compositions, formulations, Products or Licensee Owned improvement Products containing or developed using the Patents, Improvement Patents, Technology or any Improvements,

outside the Diagnostic Field of Use and the Therapeutic Field of Use. For greater clarity it is confirmed that the Reagent Field of Use shall include all uses as chemical reagents or fine chemicals and any use that is not listed in the FDA Orange Book, or the Canadian or foreign equivalent of such listing as a drug product approved for use in humans;

(ll) "**Royalty Due Dates**" means the last day of March, June, September and December of each year during the Term;

(mm) "**Sublicense Agreement**" means any agreement under which rights are granted by the Licensee to a third party under the license rights granted by UBC to Licensee hereunder for the use, research, development, co-development, partnered development, manufacture, marketing or sale of Products or granting rights to such third party in the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements;

(nn) "**Sublicensee**" means any third party who has directly or indirectly entered into a Sublicense Agreement with the Licensee, and shall include all sub-sublicensees of a particular Sublicensee;

(oo) "**Sublicensing Fees**" means all initial or periodic license fees, development or commercialization fees, milestone payments or other payments received by the Licensee from a Sublicensee under the terms of any Sublicense Agreement to the extent such payments are based upon and are in consideration for the grant by Licensee of the sublicense under Licensee's license rights granted by UBC under this Agreement, whether received in cash or other form (such as shares or other securities or other consideration, which for purposes of this Agreement shall be valued at fair market value at the time of receipt by Licensee), but excluding royalties calculated on the sales or other commercial disposition of Products or Licensee Owned Improvement Product by any Sublicensee. For greater clarity, it is confirmed that Sublicensing Fees will include any fees that are characterized as research or development fees ***but solely*** to the extent such fees are in excess of the direct reimbursement for the actual costs of research and development incurred by the Licensee pursuant to a written research plan

and agreement received by the Licensee from any Sublicensee relating to the Licensed Patents, Technology, Improvements, Products or any Licensee Owned Improvement Products (which direct reimbursement may be in the form of reasonable and typical FTE rates), and that any amounts received by Licensee from a Sublicensee as reimbursement for the actual costs of such research and development shall not be included in the term "Sublicensing Fees". For further clarity, it is agreed that any amounts received by Licensee as consideration for issuance by Licensee to a Sublicensee of Licensee stock sold to Sublicensee at the fair market value of such stock, or as an arms length loan on commercially reasonable terms, or as direct reimbursement of patent prosecution costs, or as payment of a share of amounts recovered in enforcing patent or other intellectual property rights, shall be excluded from and not be included in the term "Sublicensing Fees";

(pp) "**Technology**" means all knowledge, know-how and/or technique or techniques invented, developed and/or acquired before the Effective Date by UBC relating to any of inventions disclosed in the Patents, and including the technology and materials described in Schedule "**A**", as amended from time to time, including, without limitation all related research, data, specifications, instructions, manuals, papers or other related materials of any nature at all, whether written or otherwise, and UBC's Confidential Information;

(qq) "**Term**" is defined in Article 17.1;

(rr) "**Therapeutic Field of Use**" means any use of:

(i) the Patents, Improvement Patents, Technology or any Improvements, or

(ii) any compositions, formulations, Products or Licensee Owned Improvement Products containing or developed using the Patents, Improvement Patents, Technology or any Improvements,

for use in the cure, mitigation, treatment, or prevention of disease in humans, including the use of any Product or Licensee Owned Improvement Product that is the subject of an FDA-Approved New Drug Application and which is listed in the FDA Orange Book, or the Canadian or foreign equivalent;

(ss) "**UBC Improvements**" means improvements, variations, updates, modifications, and enhancements relating to the Patents or Technology made, discovered and/or acquired by UBC at any time after the Effective Date, which are claimed or covered by the Patents, or if not claimed or covered by the Patents, are analogs of and synthesized based upon a compound, group of compounds, or pharmacophore that is claimed or covered by the Patents in existence prior to the initial manufacture or discovery of such new compounds. For clarity UBC Improvements do not include New Technology;

(tt) "**UBC Trade-marks**" means any mark, trade-mark, service mark, logo, insignia, seal, design, symbol or device used by UBC in any manner at all;

(uu) "**Valid Claim**" is defined in Article 5.2(d); and

(vv) "**Withholding Taxes**" is defined in Article 5.7.

2.0 PROPERTY RIGHTS IN & TO THE PATENTS, TECHNOLOGY AND IMPROVEMENTS

2.1 UBC and Licensee acknowledge and agree that, as between the parties:

(a) UBC owns all right, title and interest in and to the Licensed Patents, Technology, all UBC Improvements, all Assigned Licensee Improvements, and all New Technology, subject only to the licensee rights and other rights granted by UBC to Licensee under this Agreement; and

(b) the Licensee owns all right, title and interest in and to the Licensee Owned Improvements and all patents that claim or cover such Licensee Owned Improvements.

2.2 The parties will each at the request of the other sign all documents as may be reasonably required to ensure that ownership of the Technology, Improvements, Patents, Improvement Patents and New Technology are assigned to and remain with the party identified in Article 2.1 as owning such Technology, Patents, Improvement Patents, and New Technology.

2.3 On the last working day of June and December of each year during the Term, the Licensee will give notice to UBC of the details of all Assigned Licensee Improvements and Licensee Owned Improvements that the Licensee and/or any Sublicensees of the Licensee have made or developed during the previous six month period.

2.4 UBC hereby grants to the Licensee an option (the "**Option**") to obtain an exclusive, world-wide license to use and sublicense any New Technology (and including any patent or other intellectual property covering such New Technology), provided that:

(a) the Investigator is at the time of the discovery of such New Technology and its disclosure to UBC still an employee of UBC and subject to UBC's policies in making such discovery, including UBC's Patents and Licensing Policy 88; and

(b) the Licensee is not at the time of exercise of the Option in material breach of this Agreement or any other agreement with UBC.

To the extent that there are any inconsistencies between the Option as set out in this Agreement and the terms of any collaborative research agreement under which the development of any New Technology was sponsored by the Licensee, the terms of the collaborative research agreement will prevail.

2.5 The period for exercise by the Licensee of the Option, with respect to particular New Technology, will be 6 months starting from the date of disclosure by UBC to the Licensee of the particular New Technology (the "**Option Period**" with respect to such New Technology). Such disclosure shall include reasonably relevant information relating to the New Technology as is in the possession of UBC's Industry Liaison Office and which it is able to disclose to the Licensee.

2.6 In order to exercise the Option with respect to particular New Technology disclosed by UBC to Licensee, the Licensee will sign and deliver to UBC prior to the expiry of the Option Period applicable to such New Technology a Notice of Exercise of Option in the form attached as Schedule "**B**", together with a summary business plan prepared in accordance with generally accepted business standards that describes the steps that the Licensee proposes to

take to commercially exploit the New Technology including relevant market information and revenue projections.

2.7 During the Option Period as to a particular New Technology, UBC will not grant any license to commercially exploit the New Technology to any other party. If the Licensee does not exercise the Option within the Option Period in accordance with Article 2.6 as to such New Technology, the parties agree that the Option will expire with respect to such item of New Technology, and UBC will thereafter be free to deal with and commercialize such New Technology in any way, and without further obligation to the Licensee.

2.8 If the Licensee validly exercises the Option for a particular item of New Technology as provided in Article 2.6, then the parties will negotiate exclusively and in good faith to determine the specific terms and conditions on which a new exclusive (or, if elected by Licensee, non-exclusive) license will be granted by UBC to the Licensee under such New Technology. Such new license agreement shall be on commercially reasonable terms typical for similar license agreements, including commercially reasonable royalty rates and other financial terms and shall be generally consistent with the terms and conditions of this Agreement. The parties shall seek in good faith and using diligent efforts to reach agreement on such terms and to enter into such new license agreement as soon as practicable after Licensee exercises the Option.

2.9 If UBC and the Licensee are unable, despite each party using good faith efforts, to agree upon the specific terms and conditions of a new license agreement within a period of 6 months after the date when the Licensee exercises the Option pursuant to Article 2.6 with respect to a particular item of New Technology, then the Option as to such particular New Technology shall expire.

2.10 Any new license granted by UBC with respect to any New Technology shall provide UBC the right in perpetuity to use the New Technology without charge in any manner whatsoever for research, scholarly publication, educational or other non-commercial uses.

3.0 GRANT OF LICENSE

3.1 Subject to Article 3.4, UBC grants to the Licensee the worldwide, exclusive license to use, practice and sublicense the Licensed Patents, Technology, UBC Improvements and any Assigned Licensee Improvements, and to research, develop, manufacture, have made, distribute, use, import, offer for sale and sell the Products and Licensee Owned Improvement Products on the terms and conditions set out in this Agreement.

3.2 The license granted under this Agreement is granted only to the Licensee and not to any Affiliated Companies.

3.3 The Licensee will not enter into a Naked Cross-License Agreement involving the Licensed Patents, Technology, UBC Improvements, or any Assigned Licensee Improvements without the prior written consent of UBC, such consent not to be unreasonably withheld. For the purposes of this section a "Naked Cross-License Agreement" means an agreement between the Licensee and a third party possessing certain technology, that:

(a) involves the Licensee granting license rights under the Licensed Patents, Technology, UBC Improvements, or any Assigned Licensee Improvements to such third party, and such third party granting to the Licensee, in consideration of

such license rights granted by Licensee, license right under the third party's technology, and

(b) is entered into by the Licensee and such third party without the third party agreeing to pay to the Licensee and consideration other than the exchange of license rights described in subsection (a) of this definition.

3.4 The Licensee acknowledges and agrees that, notwithstanding the exclusive license granted by UBC under Article 3.1, UBC may use the Patents, Licensed Patents, Technology and any Improvements (other than Licensee Owned Improvements) without charge in any manner at all for research, scholarly publication, educational and all other non-commercial uses.

3.5 As a condition of UBC granting this license, the Licensee agrees to pay to UBC an initial license fee of **[*]** (U.S. funds) (the "**Initial License Fee**"). The Initial License Fee will be paid concurrently with the execution of this Agreement, and will not be refunded to the Licensee (in whole or in part) under any circumstances.

3.6 UBC may register a financing statement regarding this Agreement under the *Personal Property Security Act* of British Columbia and/or under similar legislation in those jurisdictions in which the Licensee carries on business and/or has its chief place of business.

3.7 The Licensee will use reasonable efforts to give notice to UBC if it is carrying on business and/or locates its chief place of business in a jurisdiction outside British Columbia before starting business in that other jurisdiction. If UBC has registered a financing statement under Article 3.6, the Licensee will use reasonable efforts to provide UBC notice within 45 days of any change in jurisdiction.

3.8 On execution of this Agreement, the Licensee will pay to UBC the sum of **[*]** (Canadian Funds) to reimburse UBC for all outside patent expenses invoiced to UBC or its agents, directly in connection with the filing or prosecution of the Patents prior to February 1, 2007, and UBC will confirm such amount by providing to the Licensee copies of the invoices submitted to UBC for such activities. To the extent that any such patent expenses have not been invoiced to UBC prior to February 1, 2007, and are therefore not included in the **[*]** (Canadian Funds), amount, and to the extent that UBC incurs any additional outside patent expenses after the Effective Date for filing or prosecution of the Patents, the Licensee agrees that it will within 30 days of presentation by UBC to the Licensee of the invoices for such activities, reimburse to UBC the balance of such patent expenses.

4.0 SUBLICENSING

4.1 The Licensee may enter into Sublicense Agreements with its Affiliated Companies or any other third party, without UBC's prior consent, provided that each such Sublicense Agreement is consistent with the terms and conditions contained in this Agreement, and that each such Sublicense Agreement shall contain the mandatory sublicensing provisions contained in Schedule "**C**" which provisions shall not be materially revised or amended without first obtaining the prior written consent of UBC, which consent shall not be unreasonably withheld. Within 10 business days of signing any Sublicense Agreement, the Licensee will provide to UBC a fully executed unredacted copy of each Sublicense Agreement and a certification signed by a senior officer of the Licensee that such Sublicense Agreement is consistent with the terms and conditions of this Agreement and includes the mandatory sublicensing provisions contained in Schedule "**C**".

4.2 Any Sublicense Agreement granted by the Licensee will be granted only to the Sublicensee and cannot be assigned or further sub-sublicensed without the prior written consent of UBC, such consent not to be unreasonably withheld.

4.3 Promptly after executing a Sublicense Agreement, the Licensee will use reasonable efforts to give notice to UBC of the jurisdictions in which the Sublicensee is carrying on business. If the Licensee, during the term of the Sublicense Agreement, becomes aware of the Sublicensee carrying on business in another jurisdiction, then the Licensee will use reasonable efforts to give notice to UBC within 45 days.

5.0 ROYALTIES

5.1 In consideration of the license granted under this Agreement, the Licensee will pay to UBC a royalty equal to:

(a) **[*]** of the Net Revenue arising from sales of Products in **[*]** in **[*]** where **[*]**;

(b) **[*]** of the Net Revenue arising from sales of:

(i) Licensee Owned Improvement Products in the **[*]**, and

(ii) Products in the **[*]** in **[*]** where **[*]**;

(c) **[*]** of the Net Revenue arising from sales of Products **[*]** in **[*]** where **[*]**;

(d) **[*]** of the Net Revenue arising from sales of:

(i) Licensee Owned Improvement Products in the **[*]**, and

(ii) Products in the **[*]** in **[*]** where the **[*]**;

(e) **[*]** of the Net Revenue arising from sales of Products in the **[*]** in **[*]** where **[*]**; and

(f) **[*]** of the Net Revenue arising from sales of:

(i) Licensee Owned Improvement Products in the **[*]**, and

(ii) Products in the **[*]** in **[*]** where the **[*]**.

5.2 For greater clarity it is confirmed that:

(a) the royalties set out in Article 5.1 will be payable by the Licensee on all Revenue regardless of whether such Revenue is received by the Licensee or any Sublicensee(s);

(b) "**Licensee Owned Improvement Products**" shall be defined as meaning products, goods or services:

(i) that are covered or claimed by, or the manufacture or use of which is covered or claimed by, a Valid Claim in a patent filed with respect to a Licensee Owned Improvement; and/or

(ii) that incorporate or are based upon any material aspect of a Licensee Owned Improvement provided that such products, goods or services are not also covered or claimed by a Patent or Licensed Patent;

(c) if any Net Revenue may be categorized as arising from one or more of the fields of use listed in Articles 5.1(a) through (f) above, then the royalty rate applicable to such Net Revenue shall be the one that is most favourable to UBC; for clarity, Licensee shall pay UBC royalties under Article 5.1 based on sales of a particular Product or Licensee Owned Improvement Product on a country by country basis at only one royalty rate, as determined under one of the subsections in Article 5.1 above (and no more than one rate with respect to sales in any single country);

(d) "**Valid Claim**" shall be defined as meaning a claim in a pending, issued or granted Patent or Improvement Patent that, at the time of sale of the applicable Product or Licensee Owned Improvement Product:

(i) has not expired, lapsed, been cancelled or become abandoned;

(ii) has not been admitted to be invalid through reissue or disclaimer or otherwise; or

(iii) has not been finally found to be invalid (or not valid) or unenforceable by an unreversed or unappealable final decision or judgment of a court or other authority or agency of competent jurisdiction.

Any claim being presented in a pending patent application that is being prosecuted in good faith shall be deemed to be the equivalent of a valid claim of an issued, unexpired patent until disallowed, rejected or abandoned.

5.3 The royalty is due and payable within 60 days of each respective Royalty Due Date and is to be calculated with respect to the Revenue in the three month period immediately before the applicable Royalty Due Date.

5.4 All royalties paid by the Licensee to UBC under this Agreement will be in Canadian dollars without any reduction or deduction of any nature or kind at all, except as provided in Section 5.7. If the Licensee or any Sublicensee receives any Revenue in a currency other than Canadian dollars, Licensee will calculate the amount of royalties owed in such currency, and such amount will then be converted to the equivalent in Canadian dollars on the date that any amount is payable to UBC, at the rate of exchange set by the Bank of Montreal for buying Canadian dollars with such currency. The amount of royalties owed in Canadian dollars resulting from the conversion is to be paid to UBC.

5.5 Products and Licensee Owned Improvement Products are deemed to have been sold by the Licensee or a Sublicensee and included in the Revenue when invoiced, delivered, shipped, or paid for, whichever is the first.

5.6 Any transaction or other commercial disposition involving the Patents, Improvement Patents, Technology, Improvements, Products or any Licensee Owned Improvement Products, between the Licensee or any Sublicensee and another person, that is not made at fair market value is deemed to have been made at fair market value, and the fair

market value of the transaction, disposition, or other dealing will be added to and deemed part of the Revenue and will be included in the calculation of royalties under this Agreement.

5.7 The parties acknowledge that, since UBC is a non-profit, tax exempt, publicly funded educational institution, and as such UBC should not be subject to any withholding or other similar taxes on any payments made by the Licensee to UBC under this Agreement. However, if Licensee determines that it is required to pay or withhold on account of UBC amounts of taxes which are otherwise payable by UBC pursuant to any applicable law, including, but not limited to, United States federal, state or local tax law ("**Withholding Taxes**"), the Licensee will inform UBC of such determination and the parties will

discuss the matter in good faith and seek diligently to determine if there is any legal mechanism (which does not impose any additional costs or burdens on Licensee) to avoid paying or withholding such Withholding Tax. Any such Withholding Taxes required by law to be paid or withheld shall be an expense of, and borne solely by UBC if UBC is the party on which the Withholding Taxes are levied, and if Licensee is required to withhold such Withholding Tax, Licensee may deduct the tax from the applicable payment, provided that Licensee submits to UBC reasonable proof of payment of such Withholding Taxes, together with an accounting of the calculations of such taxes, within 30 days after such Withholding Taxes are remitted to the proper authority. The parties will cooperate reasonably in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable law in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment.

6.0 MILESTONES AND ANNUAL PAYMENTS

6.1 In addition to all other payments due pursuant to this Agreement, the Licensee shall pay to UBC the following payments

(a) if the Licensee has not executed a Sublicense Agreement for use of the Licensed Patents, Technology or any Improvements within the Therapeutic Field of Use, then the Licensee shall pay to UBC the applicable of the following milestone payments (the "**Milestone Payments**") on Licensee's achievement of each of the following applicable events with respect to each Product or Licensee Owned Improvement Product (the "**Milestone Events**"):

	Milestone Payment Amount (in US $)	
Milestone Event	**Product**	**Licensee Owned Improvement Product**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**
[*]	**[*]**	**[*]**

(b) subject to Article 6.2 and 6.3, all Milestone Payments shall be payable by the Licensee to UBC within 30 days of December 31st of the year during which the applicable Milestone Event was achieved;

(c) if the Licensee has executed a Sublicense Agreement for use of the Licensed Patents, Technology or any Improvements within the Therapeutic Field of Use, and in addition to entering into such Sublicense, the Licensee develops one or more Products or Licensee Owned Improvement Products within the Therapeutic Field of Use independent of the Sublicense Agreement, then the Licensee will pay to UBC the applicable Milestone Payments set out in Article 6.1(a) on the Licensee's achievement of the Milestone Events for such Products or Licensee Owned Improvement Products being developed by the Licensee independent of the Sublicense Agreement and on executing any further Sublicense Agreement with respect to such Products or Licensee Owned Improvement Products being developed by the Licensee, the Licensee will pay to UBC the greater of the Milestone Payments or Sublicensing Fees received by the Licensee in accordance with either Article 6.2 or 6.3 dependent on the stage of development of such Products or Licensee Owned Improvement Products as of the date that such further Sublicense Agreement is entered into. Such payments shall be paid to UBC regardless of whether there are any amounts payable by the Licensee under Article 6.2 and 6.3 with respect to the Sublicensee's development of different Products or Licensee Owned Improvement Products developed under the Sublicense Agreement;

(d) each year during the Term of this Agreement the Licensee will also pay to UBC on the dates set out below an annual payment equal to the amounts set out below (the "**Annual Payment**"). This Annual Payment will not be refunded to the Licensee (in whole or in part) under any circumstances:

(i)	**[*]**	**[*]**
(ii)	**[*]**	**[*]**
(iii)	**[*]**	**[*]**
(iv)	**[*]**	**[*]**
(v)	**[*]**	**[*]**
(vi)	**[*]**, and on **[*]**, of each subsequent year thereafter	**[*]**

6.2 Subject to Article 6.3, if the Licensee has executed a Sublicense Agreement for use of the Licensed Patents, Technology or any Improvements within the Therapeutic Field of Use, then upon the Sublicensee achieving a Milestone Event (as listed in the schedule in Article 6.1(a) above), the Licensee will pay to UBC the greater of either:

(a) the Milestone Payment identified in the **[*]** column of the table in Article 6.1(a) above with respect to achievement of such Milestone Event, and

(b) a percentage of the total Sublicensing Fees received by Licensee from its Sublicensee under the terms of such Sublicense Agreement (which percentage will be determined in accordance with the following schedule) during the applicable period as provided expressly in Section 6.4:

Milestone Event	Percentage of Sublicensing Fees
If the Sublicense Agreement is executed prior to **[*]**	**[*]**
If the Sublicense Agreement is executed subsequent to **[*]**	**[*]**

6.3 If the Licensee has executed a Sublicense Agreement within the Therapeutic Field of Use, that grants such Sublicensee a license with respect to the Licensee Owned Improvements, and such Sublicense Agreement does not include a grant of any rights with respect to the Licensed Patents, Technology or any Improvements (other than the Licensee Owned Improvements) then upon the Sublicensee achieving a Milestone Event (as listed in the schedule in Article 6.1(a) above), the Licensee will pay to UBC the greater of either:

(a) the Milestone Payment identified in the "Licensee Owned Improvement Product" column of the table in Article 6.1(a) above with respect to achievement of such Milestone Event, and

(b) a percentage of the total Sublicensing Fees received by Licensee from its Sublicensee under the terms of such Sublicense Agreement (which percentage will be determined in accordance with the following schedule) during the applicable period as provided expressly in Section 6.4:

Milestone Event	Percentage of Sublicensing Fees
If the Sublicense Agreement is executed prior to **[*]**	**[*]**
If the Sublicense Agreement is executed subsequent to **[*]**	**[*]**

6.4 With respect to all Milestone Events achieved by a particular Sublicensee under a Sublicense Agreement during a particular calendar year, Licensee shall make the determination under Article 6.2 or 6.3, of whether Licensee will make payments under Article 6.2(a) or 6.3(a) above for such Milestone Event achievements (i.e., make the Milestone Payments under Article 6.1(a) owed with respect to such Milestone Events) or will pay a percentage of the Sublicensing Fees received under Article 6.2(b) or 6.3(b) from such Sublicensee, on an annual basis and will make such calculation effective as of December 31st of such year. For this purpose, the Licensee will prepare and deliver to UBC within 30 days of December 31st of each year a report and an accounting statement which sets out a comparison of:

(a) all of the Sublicensing Fees received by the Licensee from such Sublicensee during the period starting on the later of (i) the execution of the Sublicense Agreement or (ii) December 31 of the year of achievement by the Sublicensee of the last Milestone Event in respect of which the Licensee has made a payment to UBC under Article 6.2 or 6.3; and ending on December 31 of the applicable year for which the report is delivered to UBC, and

(b) the Milestone Event(s) that were achieved by the Sublicensee during the calendar year period ending on such December 31; and

(c) a calculation showing the comparison of the total amounts that would be payable by Licensee under Article 6.2(a) or 6.3(a) based on achievement of such Milestone Events during such year, and the total amount that would be payable under Article 6.2(b) or 6.3(b), by applying the appropriate percentage to the total Sublicensing Fees received by Licensee from such Sublicensee during the period specified in subsection (a) above.

The Licensee will also deliver to UBC along with the report and accounting statement referred to above, the amount determined to be payable to UBC in accordance with either Article 6.2(a) or (b); or 6.3(a) or 6.3(b).

For example, if a Sublicensing Agreement is executed after **[*]**, and such Sublicensee **[*]** a Product during a particular calendar year (and that completion is the first Milestone Event achieved by such Sublicensee after executing the Sublicensing Agreement), then for achievement of such Milestone Event the Licensee will pay to UBC, under the terms of Article 6.2 and this Article 6.4, the greater of:

(i) **[*]** (the amount identified in Article 6.1(a) above for achievement of such Milestone Event) and (ii) **[*]** of all Sublicensing Fees paid to Licensee by such Sublicensee under such Sublicensing Agreement through to December 31 of such calendar year. If such Sublicensee subsequently **[*]** the same Product, then for achievement of such Milestone Event the Licensee will shall pay to UBC, under Article 6.2, the greater of: (i) **[*]** (the amount identified in Article 6.1(a) above for achievement of such Milestone Event), and (ii) an amount equal to **[*]** of all Sublicensing Fees paid to Licensee by such Sublicensee under such Sublicensing Agreement ***after*** December 31 of the year in which the **[*]** Milestone Event was achieved by such Sublicensee, ***through*** to December 31 of the calendar year in which such **[*]** Milestone Event was achieved by such Sublicensee.

6.5 The Licensee will pay to UBC, in addition to all other amounts due under this Agreement, an annual maintenance fee of U.S. **[*]** (the "**Annual Maintenance Fee**"). The Annual Maintenance Fee is payable on or before April 1 of each year during the Term, starting on April 1, 2007 and will not be refunded to the Licensee (in whole or in part) under any circumstances.

7.0 PATENTS

7.1 UBC will, on the request of the Licensee, take reasonable steps to apply for a patent with respect to the Technology, UBC Improvements, or any Assigned Licensee Improvements in the name of UBC provided that the Licensee pays all costs of applying for, registering and maintaining the patent in the jurisdictions in which the Licensee designates that a patent is required, and such patent shall be deemed included in the Licensed Patents. The Licensee will on UBC's request pay to UBC a reasonable payment as an advance against expected patent expenses over the next 3 months with respect to any such requested filing.

7.2 On the filing (thereafter including after issuance) of a Licensed Patent filed under Article 7.1, the Licensee becomes the licensee of the Licensed Patent on the terms and conditions set out in this Agreement.

7.3 Throughout the Term, the Licensee will within 30 days of presentation of receipts and/or invoices by UBC to the Licensee showing the amounts actually charged by Licensee's external patent counsel of for filing fees or similar external prosecution costs, reimburse to UBC the balance of all out-of-pocket patent filing, prosecution and maintenance costs incurred to such date regarding the Licensed Patents.

7.4 The Licensee will not contest the validity or scope of the Licensed Patents or the Technology, Improvements or any New Technology, to the extent such restriction is permitted by applicable law.

7.5 To the extent required by applicable law, the Licensee will ensure proper patent marking for all uses of the Licensed Patents licensed under this Agreement and will clearly mark the appropriate patent numbers on any Products covered by the Licensed Patents.

8.0 DISCLAIMER OF WARRANTY

8.1 Except as otherwise expressly provided in Article 8.3, UBC makes no representations, conditions or warranties, either express or implied, regarding the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products. Without limitation, UBC specifically disclaims any implied warranty, condition or representation that the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Product:

(a) correspond with a particular description;

(b) are of merchantable quality;

(c) are fit for a particular purpose; or

(d) are durable for a reasonable period of time.

UBC is not liable for any loss, whether direct, consequential, incidental or special, that the Licensee or other third parties suffer arising from any defect, error or fault of, or failure to perform by, the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products, even if UBC is aware of the possibility of the defect, error, fault or failure. The Licensee acknowledges that it has been advised by UBC to undertake its own due diligence regarding the Licensed Patents, Technology and any Improvements.

8.2 Nothing in this Agreement:

(a) constitutes a warranty or representation by UBC as to title to the Licensed Patents, Technology or any Improvements, except as provided in Section 8.3 below, or that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will not infringe the patents, copyrights, trademarks, industrial designs or other intellectual property rights of any third parties, including any patents, copyrights, trade-marks, industrial design or other intellectual property rights owned, in whole or in part, by UBC, or licensed by UBC to any third parties;

(b) constitutes an express or implied warranty or representation by UBC that the Licensee has, or will have the freedom to operate or practice the Licensed Patents, Technology or any Improvements, or the freedom to make, have made, use, sell or otherwise dispose of Products or Licensee Owned Improvement Products; or

(c) imposes an obligation on UBC to bring, prosecute or defend actions or suits against third parties for infringement of patents, copyrights, trade-marks, industrial designs or other intellectual property or contractual rights.

8.3 UBC hereby represents and warrants to Licensee that as of the Effective Date to the best of the knowledge of the UBC staff having responsibility for the commercialization of this Technology at the UBC Industry Liaison Office, and without having made any specific inquiry:

(a) as between UBC and the inventors or the Technology employed by UBC, UBC has been assigned ownership of the Technology and the Patents;

(b) UBC has corporate power and authority to grant, and is not prohibited by any legislation from granting, a license of technology under the Patents and the Technology under this Agreement; and

(c) UBC has not previously granted to any third party any license to commercially exploit the Patents and/or the Technology that materially conflict with the license rights granted to the Licensee under this Agreement.

8.4 Notwithstanding Article 8.2, if there is an alleged infringement or misappropriation of the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements or any right with respect to the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements, the Licensee may take all appropriate steps, short of starting legal action, to stop or enjoin such infringement or misappropriation of the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements, and will consult with UBC regarding such steps. If it is necessary to start any legal action to stop or enjoin any infringement or misappropriation of the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements and/or to recover damages from such infringement or misappropriation, the Licensee may do so, provided that the Licensee first obtains UBC's prior written consent to initiate such action, which consent shall not be unreasonably withheld or delayed, and that the Licensee shall keep UBC reasonably informed regarding the progress of such action and indemnify UBC against any claims made against UBC by the defendant in such action based upon or relating to such action or the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements. Provided that it has first granted its prior written consent, such consent not to be unreasonably withheld, UBC agrees to reasonably co-operate to the extent of signing all necessary documents or to join as a party plaintiff if legally required. All the direct and indirect costs and expenses of Licensee in bringing and conducting the

legal action or settlement shall be paid by the Licensee including any out-of-pocket costs and expenses of UBC in its providing assistance. All recoveries from such legal action are for the benefit of, and shall be retained by, the Licensee.

8.5 If any complaint alleging infringement of any patent or other proprietary rights is made against the Licensee or a Sublicensee based upon the use of the Patents, improvement Patents, Technology or any Improvements or the manufacture, use or sale of the Products, the following procedure will be adopted:

(a) the Licensee will promptly notify UBC on receipt of the complaint and will use reasonable efforts to keep UBC reasonably informed of the actions and positions taken by the complainant and taken or proposed to be taken by the Licensee on behalf of itself or a Sublicensee (to the extent such information can be disclosed without breaching confidentiality obligations or court orders or destroying privilege);

(b) except as provided in Article 8.5(d), all costs and expenses incurred by the Licensee or any Sublicensee in investigating, resisting, litigating and settling the complaint, including the payment of any award of damages and/or costs to any third party, will be paid by the Licensee or any Sublicensee, as the case may be;

(c) Licensee shall not make any final disposition of the complaint in a manner that materially negatively impacts the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements without full consultation with, and approval by, UBC, such approval not to be unreasonably withheld;

(d) UBC may elect to participate as a party in any litigation involving the complaint to the extent that the court may permit, *provided that* UBC shall not take any actions that materially negatively impact Licensee's interests under this Agreement or in such litigation, and any direct additional expenses incurred by the Licensee as the result of such participation will be paid by UBC (subject to the possibility of recovery of some or all of the additional expenses from the complainant); and

(e) the Licensee will pay all royalties payable under Article 5.1 of this Agreement to UBC in trust from the date UBC receives notice of the complaint and until a resolution of the complaint has been finalized. if the complainant is successful, then the royalties paid to UBC in trust under this Article 8.5(e) will be returned to the Licensee, provided that the amount being returned to the Licensee is no more than the amount paid by the Licensee to the complainant in the settlement or other disposition of the complaint. If the complainant does not succeed, then UBC retains all royalties paid to it under this Article 8.5(e).

9.0 INDEMNITY & LIMITATION OF LIABILITY

9.1 The Licensee indemnifies, holds harmless and defends UBC, its Board of Governors, officers, employees, faculty, students, invitees and agents (the "**Indemnitees**") against any and all third party claims (including all associated legal fees and disbursements actually incurred) against any such Indemnitee arising out of the exercise by Licensee (or its Sublicensees) of any rights granted to Licensee under this Agreement, including without limitation against any damages or losses, consequential or otherwise, arising from any third party claim based in any manner at all from or out of the use of the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Product licensed under this Agreement, by the Licensee or its Sublicensees or their customers or end-users.

9.2 UBC's total liability, whether under the express or implied terms of this Agreement, in tort (including negligence) or at common law, for any loss or damage suffered by the Licensee, whether direct, indirect or special, or any other similar damage that may arise or does arise from any breaches of this Agreement by UBC, its Board of Governors, officers, employees, faculty, students or agents, is limited to **[*]**, less amounts actually paid by UBC to the inventors of the Licensed Patents, Technology or Improvements out of such payments received by UBC from the Licensee based on such inventorship in accordance with UBC's policies regarding payments to its inventors, and *provided that* any such liability on the part of UBC in excess of CDN. **[*]** may be recovered by the Licensee solely out of, and as a set off against, amounts payable by the Licensee to UBC under this Agreement after the date of any award of such damages or other liability.

9.3 Subject to Article 9.1, each Party acknowledges and agrees that the other Party will not be liable for any special, punitive, consequential or incidental damages arising from any breach or breaches of this Agreement.

9.4 Notwithstanding the termination or expiration of this Agreement, the rights and obligations in Article 9 will survive and continue to bind the each party and its successors and assigns.

10.0 PUBLICATION & CONFIDENTIALITY

10.1 Each party will keep and use the other party's Confidential Information in confidence and will not, without the other party's prior written consent, disclose the other party's Confidential Information to any person or entity, except to the party's permitted sublicensees (if such party is Licensee) directors, officers, employees, faculty, students and professional advisors who require the Confidential Information to assist such party in performing its obligations or exercising its rights under this Agreement. Each party will use the other party's Confidential Information solely for the purposes permitted under this Agreement and will not, without the other party's prior written consent, use the other party's Confidential Information for any other purpose. The Licensee will maintain an appropriate internal program limiting the distribution of JBC's Confidential Information to only those Sublicensees, officers, employees and professional advisors who require such Confidential Information in performing the Licensee's obligations or exercising its rights under this Agreement and who have signed appropriate nondisclosure agreements.

10.2 Notwithstanding the foregoing, a party may disclose the other party's Confidential Information to the extent such disclosure is required by judicial or administrative process, provided that such party will promptly notify the other party of such requirement and allow it reasonable time to oppose the process before disclosing the specific Confidential Information.

10.3 UBC is not restricted from presenting at symposia, national or regional professional meetings, or from publishing in journals or other publications, accounts of its research relating to the Licensed Patents, Technology and any Improvements (other than Licensee Owned Improvements), provided that with respect to the Confidential Information only, the Licensee is provided with copies of the proposed disclosure at least 60 days before the presentation or publication date and does not, within 30 days after delivery of the proposed disclosure, give notice to UBC indicating that it objects to the proposed disclosure. Any objection to a proposed disclosure will specify the portions of the proposed disclosure considered objectionable (the "Objectionable Material"). On receiving notice from the Licensee that any proposed disclosure contains Objectionable Material, UBC and the Licensee agree to work together to revise the proposed disclosure to remove or alter the Objectionable Material in a manner acceptable to both the Licensee and UBC, in which case the Licensee will withdraw its objection. UBC is not restricted from publishing or presenting the proposed disclosure as long as the Objectionable Material has been removed. Any Objectionable Material will not be disclosed for six months from the date UBC delivered the proposed disclosure to the Licensee. After six months from the date UBC delivered the proposed disclosure to the Licensee, UBC is free to present and/or publish the proposed disclosure whether or not it contains Objectionable Material.

10.4 The Licensee requires of UBC, and to the extent permitted by law UBC agrees, that this Agreement, and each part of it, is confidential and will not be disclosed to third parties, as the Licensee claims that the disclosure would or could reveal commercial, scientific or technical information and would significantly harm the Licensee's competitive position and/or interfere with the Licensee's negotiations with prospective Sublicensees. Notwithstanding anything contained in Article 10, the Licensee acknowledges and agrees that UBC may identify the title of this Agreement, the parties to this Agreement and the names of the inventors of the Licensed Patents, Technology and any Improvements, and that UBC may also disclose to the

inventors of the Licensed Patents and Technology the amount of all payments made to UBC by the Licensee under this Agreement, the manner or method by which such payments were calculated and all Payment Reports delivered to UBC by the Licensee in connection with such payments.

10.5 Notwithstanding the termination or expiration of this Agreement, the rights and obligations in Article 10 survive and continue to bind the parties, their successors and assigns.

11.0 PRODUCTION & MARKETING

11.1 The Licensee will not knowingly use the UBC Trade-marks or make reference to UBC or its name in any advertising or publicity, without the prior written consent of UBC. Without limitation, the Licensee will not issue a press release regarding this Agreement or the 'Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements without first obtaining UBC's written approval, such approval not to be unreasonably withheld or delay, and provided that Licensee shall be permitted to make such public disclosures regarding the existence or terms of this Agreement as are required to comply with applicable law or regulation. If the Licensee is required by law or regulation to disclose the Agreement or any of its terms, the Licensee will provide UBC with reasonable prior notice to permit UBC to bring an application or other proceeding to contest the requirement.

11.2 The Licensee represents and warrants to UBC that it has the infrastructure, expertise and resources to:

(a) develop and commercialize the Licensed Patents, Technology and any Improvements;

(b) track and monitor on an ongoing basis performance under the terms of each Sublicense Agreement;

(c) monitor patent infringement regarding any patent relating to the Licensed Patents, Technology and any Improvements licensed under this Agreement; and

(d) handle the Licensed Patents, Technology and any Improvements with care and without danger to the Licensee, its employees, agents, or the public.

11.3 The Licensee agrees that it will, throughout the Term:

(a) use Commercially Reasonable Efforts to develop and commercialize the Licensed Patents, Technology and any Improvements allocating at least the same degree of diligence, expertise, infrastructure, and resources as the Licensee is allocating to other products developed and marketed by the Licensee that have a similar profit potential, are at the same stage of development, and have similar product life, patent position, market potential and regulatory issues; and

(b) use Commercially Reasonable Efforts to promote, market and sell the Product and Licensee Owned Improvement Product (once Regulatory Approval is achieved) in the applicable countries and exploit the Licensed Patents, Technology and any Improvements and to meet or cause to be met the market demand for the approved Products and Licensee Owned Improvement Products and the potential use of the Licensed Patents, Technology and any Improvements.

11.4 Without Limiting the generality of the obligations set out in Article 11.3, the Licensee will use Commercially Reasonable Efforts to **[*]** according to the following development timeline:

(a) Licensee will use Commercially Reasonable Efforts to **[*]** within **[*]** of the Effective Date;

(b) Licensee will Use Commercially Reasonable Efforts to **[*]** within **[*]** of the Effective Date;

(c) Licensee will use Commercially Reasonable Efforts to **[*]** within **[*]** of the Effective Date; and

(d) Licensee will use Commercially Reasonable Efforts to **[*]** within **[*]** of the Effective Date.

It is understood and agreed that actions by any Sublicensee may satisfy any of the above timeline matters. The Licensee further acknowledges UBC's objective in licensing the Licensed Patents, Technology and any Improvements to the Licensee is that the Licensee use Commercially Reasonable Efforts to promote, market and sell Products (once Regulatory Approval is achieved) for use in several therapeutic fields, including possible **[*]**. Therefore, if the Licensee is developing a Product for a particular therapeutic field in accordance with the timelines set out in Articles 11.4(a) through (d), but is unable to develop, or cause to be developed other Product(s) within one or more other therapeutic fields of use, then the Licensee will at the request of UBC consider in good faith the grant by the Licensee of one or more sublicenses of the Licensed Patents, Technology and any Improvements on commercially reasonable terms to a third party or parties identified by UBC as being able to develop, or cause to be developed Product(s) within one or more of the therapeutic fields of use not being exploited by the Licensee.

11.5 If UBC believes in good faith that the Licensee is in material breach of Article 11.3, UBC may give notice to the Licensee under Article 18.3, which notice shall specify particulars of the alleged breach. Within 30 days of receiving UBC's notice, the Licensee shall provide notice to UBC of its election to:

(a) proceed with remedying the breach in accordance with Article 18.3, or

(b) dispute the breach ("**Dispute**") and refer the Dispute to mediation in accordance with Articles 11.6; or

(c) accept the breach.

If the Licensee elects to proceed with remedying the breach, then the Licensee will be deemed to have waived any right to refer the matter to mediation in accordance with Article 11.6. If the Licensee fails to make an election in accordance with this Article, then the Licensee will be deemed to have accepted the breach and UBC may terminate this Agreement.

11.6 If the Licensee elects to refer the Dispute to mediation, UBC and Licensee will jointly appoint an impartial, independent mediator with (to the extent available) expertise in the research and development of pharmaceutical products and in licensing agreements regarding such activities (the "**Mediator**") within 15 days of the Licensee's election. On appointment of Mediator the following rules and procedures will govern the conduct of the parties and the Mediator before and during the mediation of a Dispute:

(a) within 15 days of the appointment of the Mediator, each party will provide to the Mediator and to the other party a written summary of its position and copies of all documents on which it intends to rely. On receiving a party's summary and documents, the other party then has 15 days to submit to the other party and the Mediator a summary of such other party's position in response to the party's position;

(b) after each of the Licensee and UBC has provided its summary and documents and response under Article 11.6(a), but not more than 60 days from the appointment of the Mediator, the parties agree to meet in the presence of the Mediator with a view to resolving the Dispute. The role of the Mediator will be to assist in negotiating a resolution of a Dispute and will not make a binding decision without the parties' prior written agreement. Each party will use good faith, diligent efforts to seek to agree to a resolution of the Dispute that is mutually satisfactory and facilitates the diligent and profitable development and commercialization of the Licensed Patents, Technology, Products and Licensee Owned Improvement Products by or on behalf of Licensee;

(c) the mediation of a Dispute may be terminated by either party, by giving notice to the other party:

(i) if the other party fails to comply with its obligations under Article 11.6; or

(ii) if the parties cannot agree on a resolution of the Dispute within 60 days from the appointment of the Mediator;

(d) any information or documents disclosed by either party under this Article 11.6 must be kept confidential and must not be used except to attempt to resolve the Dispute in the context of the mediation; and

(e) each party must bear its own costs of complying with Article 11.6 and the parties must bear equally the costs of any Mediator engaged.

11.7 If the parties cannot agree on the resolution of the Dispute within 60 days from the appointment of the Mediator, or if the mediation of the Dispute has been terminated under Article 11.6(c), then the Licensee will (counting from the end of the 60 day period) have a further 30 days to remedy the material breach in accordance with Article 18.3(a) (if such breach in fact has occurred). If the Licensee fails to remedy the breach (if such material breach in fact has occurred) within such 30 day period then UBC may terminate this Agreement, provided that it is understood and agreed if Licensee disputes that such material breach has occurred, no such termination shall occur or be permitted unless and until it is determined in a final judgment (which is no longer subject to any appeal) that a material breach occurred and has not been cured by Licensee.

12.0 ACCOUNTING RECORDS & REPORTS

12.1 The Licensee will maintain at its principal place of business, or another place as may be most convenient, separate accounts and records of all Revenues, Sublicensing Fees, Sublicense Agreements and all business done in connection with the Patents, Improvement Patents, Technology or any Improvements. The accounts and records will be in sufficient detail to enable proper returns to be made under this Agreement and the Licensee will cause its Sublicensees to keep and deliver to the Licensee similar accounts and records.

12.2 The Licensee will complete and deliver to UBC:

(a) within 60 days of each and every Royalty Due Date, a completed Payment Report in the form attached as Schedule "**D**", (or an amended form as required by UBC from time to time) together with the royalty payable under this Agreement. A separate Payment Report shall be

prepared and delivered for each Sublicensee and Sublicense Agreement, including an accounting statement setting out in detail how the amount of Revenue received by such Sublicensee was determined and identifying each Sublicensee and the location of the business of each Sublicensee. The first Payment Report will be submitted within 60 days of the first Royalty Due Date after the receipt of the first Revenue, and thereafter a Payment Report shall be delivered every three months regardless of whether any Revenue was received in the preceding period; and,

(b) on or before December 1st of each year during the Term, starting on December 1, 2007 an Annual Report in the form attached as Schedule "**D**" (or an amended form as required by UBC from time to time).

12.3 The calculation of royalties will be carried out in accordance with generally accepted accounting principles in the United States, or the standards and principles adopted by the U.S. Financial Accounting Standards Board applied on a consistent basis.

12.4 The Licensee will retain the accounts and records referred to in Article 12.1 for at least 6 years from when they were made and will permit a certified public accountant from a nationally-recognized accounting firm selected by UBC, to inspect, at UBC's expense, the accounts and records during the Licensee's normal business hours. The Licensee will provide to accountant access to all such accounts and records as necessary to verify the accounts and records (including the accounts and records pertaining to Revenue received by any Sublicensee(s)) and will allow copies to be made of the accounts, records and agreements. If an inspection of the Licensee or Sublicensee's records by such accountant shows an underreporting or underpayment by the Licensee of any amount to UBC, by more than five percent (5%) for any 12 month period, then the Licensee will reimburse UBC for the cost of the inspection as well as pay to UBC any amount found due (including any interest) within 30 days of notice by UBC to the Licensee. If such inspection shows an overpayment by Licensee, Licensee may credit such overpayment against any other amounts owed to UBC, *provided that* if there are no more payments owed then UBC shall reimburse Licensee for the amount of such overpayment.

12.5 Any inspection under Article 12.4 shall be subject to a confidentiality obligation under which the inspecting accountant shall be under a confidentiality agreement to ensure that all information provided to such Agreement under such Article remains confidential and is treated as confidential by such accountant provided that such accountant may disclose to UBC whether the royalty payments by Licensee are accurate including all documentation supporting the accountant's determination, and any extent of any underpayment or overpayment.

13.0 INSURANCE

13.1 During the Term, and for a period of three years thereafter, the Licensee will procure and maintain insurance (including public liability and commercial general liability insurance and insurance covering product liability), as would be acquired by a reasonable and prudent businessperson carrying on a similar line of business at a similar stage of development,

such insurance being at a minimum sufficient to cover Licensee's indemnification obligations under Section 9.1.

13.2 Without limiting Article 13.1, one month before the start of any Human Clinical Trials:

the Licensee will give notice to UBC of the terms and amount of the product liability, clinical trials, public liability, and commercial general liability insurance and such other types of insurance which it has placed. This insurance will:

(a) be placed with a reputable and financially secure insurance carrier;

(b) include UBC, its Board of Governors, faculty, officers, employees, students and agents as additional insureds;

(c) provide coverage regarding all activities under this Agreement;

(d) include a waiver of subrogation against UBC, and a severability of interest and cross-liability clauses; and

(e) provide that the policy cannot be cancelled or materially altered except on at least 30 days' prior notice to UBC.

13.3 UBC may from time to time request reasonable amendments to the terms or the amount of coverage contained in the Licensee's insurance policy, and Licensee will use reasonable efforts to accommodate such reasonable requests. The Licensee will provide to UBC for its approval certificates of insurance evidencing the coverage seven days before the earlier of any Human Clinical Trials. The Licensee will not:

(a) start any Human Clinical Trials, or

(b) sell any Product or Licensee Owned Improvement Products

at any time unless, a certificate of insurance has been provided and approved by UBC, and the insurance outlined in Article 13.2 is in effect.

13.4 The Licensee will also require each Sublicensee to procure and maintain:

(a) public liability and commercial general liability insurance and such other types of insurance as would be acquired by a reasonable and prudent businessperson carrying on a similar line of business; and

(b) in any event, one month before the start of any Human Clinical Trials by the Sublicensee, product liability, clinical trials, public liability and commercial general liability insurance in reasonable amounts, with a reputable and financially secure insurance carrier.

The Licensee will ensure that all Sublicensees' policies of insurance include UBC, its Board of Governors, faculty, officers, employees, students and agents as additional insureds.

14.0 ASSIGNMENT & CHANGE OF CONTROL

14.1 The Licensee will not assign or transfer this Agreement or any of its obligations under this Agreement without the prior written consent of UBC, such consent not to be

unreasonably withheld or delayed, provided that Licensee may assign this Agreement without such consent to its Affiliate Company or to its successor in interest in connection with the merger, acquisition or sale of all or substantially all of Licensee's assets, so long as such assignee provides to UBC in writing its agreement to undertake and perform all of Licensee's obligations under this Agreement as the assignee of Licensee entire interests in the Agreement.

14.2 UBC will have the right to assign its rights, duties and obligations under this Agreement to a company of which it is the sole shareholder, or a society which it has incorporated or which has purposes which are consistent with the objectives of UBC. If UBC makes such an assignment, **[*]**, provided that UBC assigns to such company or society the entire right, title and interest in and to all the Licensed Patents, Technology, UBC Improvements and any Assigned Licensee Improvements and the company or society, as the case may be, signs a written agreement which provides that the company or society assumes all obligations or covenants from UBC and that the Licensee retains all rights granted to the Licensee under this Agreement.

15.0 GOVERNING LAW

15.1 This Agreement is governed by, and will be construed in accordance with, the laws of the Province of British Columbia and the federal laws of Canada, without regard to any conflicts of law rules or principles that would require application of different law. All parties agree that by executing this Agreement they have attorned to the jurisdiction of the Supreme Court of British Columbia.

16.0 NOTICES

16.1 All reports and notices or other documents that a party is required or may want to deliver to any other party will be delivered:

(a) in writing; and

(b) either by personal delivery or by registered or certified mail at the address for the receiving party set out in Article 16.2 or as varied by any notice.

Any notice personally delivered is deemed to have been received at the time of delivery. Any notice mailed in accordance with this Article 16.1 is deemed to have been received at the end of the fifth day after it is posted.

16.2 The address for delivery of notices and instructions for making payments to UBC are set out in the attached Schedule "**F**". The address for delivery of notices to the Licensee is set out below:

Nicholas N. Vahanian, Chief Medical and Operations Officer
NewLink Genetics Corporation
Iowa State University Research Park
2901 South Loop Drive, Suite # 3900
Ames, Iowa 50010

Telephone: 515-296-5555
Fax: 515-296-5557

17.0 TERM

17.1 The term (the "**Term**") of this Agreement starts on the Effective Date and ends on:

(a) the day that is exactly 20 years later; or

(b) the expiry of the last Licensed Patent,

whichever is last to occur, unless terminated earlier under Article 18.

18.0 TERMINATION OF AGREEMENT

18.1 This Agreement automatically and immediately terminates without notice to the Licensee if any bankruptcy proceeding under the bankruptcy laws of the United States is started by or against the Licensee.

18.2 UBC may, at its option, immediately terminate this Agreement by giving notice to the Licensee if one or more of the following occurs:

(a) the Licensee makes or suffers the appointment of a receiver or a receiver manager with control of all or substantially all of Licensee's assets; the termination of all or substantially all of the Licensee's employees; or the Licensee ceasing or initiating a program intending to cease carrying on business;

(b) any resolution is passed or order made or other steps taken for the winding up, liquidation or other termination of the existence of the Licensee;

(c) if any Sublicensee is in material breach of its Sublicense Agreement (and such breach is causing harm to UBC), and the Licensee fails on receiving notice from UBC to take all commercially reasonable steps under the terms of the Sublicense Agreement to cause such Sublicensee to cure such breach; and

(d) if the Licensee, or any Affiliated Company, is in material breach of, any other agreement between the Licensee or such Affiliated Company and UBC and the material breach has not been cured within the time provided for the curing of such breach under the terms of the other agreement.

18.3 Other than as set out in Articles 18.1 and 18.2, a party may terminate this Agreement for any material breach by the other party of its material obligation under this Agreement *provided that* such material breach is not cured by the breaching party after such party provides the following notice to the party in breach:

(a) 45 days notice (which notice provides particulars of the specific breach) in the case of any breach which can reasonably be remedied within 45 days of the delivery of such notice; or

(b) if the breach cannot be remedied within 45 days and the breach is not remedied within such further period as may be reasonably necessary, or within 90 days after receipt of notice (which notice provides particulars of the specific breach), whichever is sooner.

18.4 If this Agreement is terminated under Article 18.1 to 18.3, the Licensee will make all outstanding royalty and other payments to UBC under Articles 5 and 6 that have accrued and are owed prior to the date of termination, and UBC may proceed to enforce payment of all outstanding royalties or other monies owed to UBC that have accrued and are owed prior to the date of termination, and each party may exercise any or all of the rights and remedies available under this Agreement or otherwise available by law or in equity, successively or concurrently, at the option of such party. Within five days of the Effective Termination Date, the Licensee will deliver to UBC all Licensed Patents, Technology, UBC Improvements and any Assigned Licensee Improvements in its possession or control and has no further right of any nature at all in the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements.

18.5 The Licensee and all Sublicensees will cease to use the Licensed Patents, Technology, UBC Improvements or any Assigned Licensee Improvements in any manner at all or to manufacture or sell the Products within five days from the Effective Termination Date. The Licensee will then deliver to UBC an accounting within 30 days from the Effective Termination Date. The accounting will specify the inventory or stock of Products manufactured and remaining unsold on the Effective Termination Date. Without limitation, if this Agreement is terminated under Article 18.1, no Products will be sold without the prior written consent of UBC. The Licensee will continue to make royalty and other payments to UBC in the same manner specified in Articles 5 and 6 on all Products that are sold in accordance with this Article 18.5, notwithstanding anything contained in, or any exercise of rights by UBC, under Article 18.4.

18.6 Notwithstanding the termination or expiration of this Agreement, Article 12 remains in full force and effect until 6 years after:

(a) all payments of royalty required to be made by the Licensee to UBC under this Agreement have been made by the Licensee to UBC; and

(b) any other claim or claims of any nature or kind at all made by UBC against the Licensee under this Agreement has been settled or resolved in court.

19.0 MISCELLANEOUS COVENANTS OF LICENSEE

19.1 The Licensee represents and warrants to UBC that the Licensee is a corporation duly organized, existing and in good standing under the laws of Iowa and has the power, authority and capacity to enter into this Agreement and to carry out the transactions contemplated by this Agreement, all of which have been duly and validly authorized by all requisite corporate proceedings.

19.2 The Licensee will comply with all applicable laws, regulations and ordinances, whether Federal, State, Provincial, County, Municipal or otherwise, with respect to the Patents, Improvement Patents, Technology and any Improvements and this Agreement.

19.3 The royalties specified in this Agreement are exclusive of taxes. If UBC is required to collect a tax to be paid by the Licensee or any of its Sublicensees, the Licensee will pay the tax to UBC on demand.

19.4 The Licensee will pay interest on all amounts due and owing to UBC under this Agreement but not paid by the Licensee on the due date, at the rate of 12.68% per annum, calculated annually not in advance. The interest accrues on the balance of unpaid amounts from time to time outstanding, from the date on which portions of the amounts become due and owing until payment in full.

20.0 MANAGEMENT OF CONFLICTS OF INTEREST

20.1 The Licensee acknowledges that it is aware of UBC's Conflict of Interest Policy #97, Patent and Licensing Policy #88 and Research Policy #87 (http://www.policy.ubc.ca/), and that UBC may amend these policies or introduce new policies from time to time.

20.2 Subject to Article 20.3 the Licensee and UBC agree, that:

(a) the facilities and research programs of the Licensee will be conducted independently of all UBC facilities, faculty, students or staff, and in particular, independently of and from the Investigator and the laboratory facilities made available to the Investigator by reason of the Investigator's employment at UBC;

(b) no students, post-doctoral fellows or other UBC staff will participate or be involved in the Licensee's research, projects or utilize its facilities; and

(c) any disclosures of inventions made by the Investigator to the Licensee will be immediately forwarded by the Licensee to UBC.

20.3 The Licensee and UBC may, from time to time, enter into written agreements to permit activities which would otherwise be prohibited by Article 20.2.

21.0 GENERAL

21.1 Nothing contained in this Agreement is to be deemed or construed to create between the parties a partnership or joint venture. No party has the authority to act on behalf of any other party, or to commit any other party in any manner at all or cause any other party's name to be used in any way not specifically authorized by this Agreement.

21.2 Subject to the limitations in this Agreement, this Agreement operates for the benefit of and is binding on the parties and their respective successors and permitted assigns.

21.3 No condoning, excusing or overlooking by any party of any default, breach or non-observance by the other party at any time or times regarding any terms of this Agreement operates as a waiver of that party's rights under this Agreement. A waiver of any term, or right under, this Agreement will be in writing signed by the party entitled to the benefit of that term or right, and is effective only to the extent set out in the written waiver.

21.4 No exercise of a specific right or remedy by any party precludes it from or prejudices it in exercising another right or pursuing another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.

21.5 All terms which require performance by the parties after the expiry or termination of this Agreement, will remain in force despite this Agreement's expiry or termination for any reason.

21.6 Part or all of any Article that is indefinite, invalid, illegal or otherwise voidable or unenforceable may be severed and the balance of this Agreement will continue in full force and effect.

21.7 The Licensee acknowledges that UBC has represented to Licensee that the law firm of Richards Buell Sutton LLP has acted solely for UBC in connection with this Agreement and that all other parties have been advised to seek independent legal advice.

21.8 This Agreement sets out the entire understanding between the parties and no changes are binding unless signed in writing by the parties to this Agreement.

21.9 Time is of the essence of this Agreement.

21.10 Unless the contrary intention appears, the singular includes the plural and vice versa and words importing a gender include other genders.

SIGNED BY THE PARTIES AS AN AGREEMENT on the 27 day of February, 2007, but effective as of the Effective Date.

SIGNED FOR AND ON BEHALF of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatories:

/s/ Barbara M. Campbell
Authorized Signatory

Barbara M. Campbell
Associate Director
University — Industry Liaison Office

Authorized Signatory

SIGNED FOR AND ON BEHALF of
NEWLINK GENETICS CORPORATION
by its authorized signatories:

/s/ Nicholas N. Vahanian
Authorized Signatory

Nicholas N. Vahanian, Chief Medical & Operations Officer
Please print Name and Title of Signatory

Authorized Signatory

Please print Name and Title of Signatory

CONFIDENTIAL

SCHEDULE "A"

DESCRIPTION OF "PATENTS" AND "TECHNOLOGY"

UBC File #	Inventor(s)	Description	Patent #
[*]	**[*]**	Indoleamine 2,3-Dioxygenase **[*]**	**[*]** Indoleamine 2,3-Dioxygenase **[*]**

SCHEDULE "B"

NOTICE OF EXERCISE OF OPTION

TO: THE UNIVERSITY OF BRITISH COLUMBIA

NEWLINK GENETICS CORPORATION hereby exercises the Option provided for in the License Agreement dated , 2006 (the "**License Agreement**") to license the following New Technology:

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[IDENTIFY THE NEW TECHNOLOGY IN RESPECT OF WHICH NEWLINK IS INTENDING TO EXERCISE ITS OPTION]

upon the terms and conditions contained in Articles 2.4 et seq. of the License Agreement between NewLink Genetics Corporation and The University of British Columbia dated , 2006.

Attached hereto as is a Business Plan prepared in compliance with the License Agreement.

CONFIDENTIAL

SCHEDULE "C"

MANDATORY SUBLICENSING PROVISIONS

1. The Sublicense Agreement shall be personal to the Sublicensee, and shall not contain the right to grant any further sub-sublicenses and shall not be assignable without the prior written consent of UBC, such consent not to be unreasonably withheld], except that the Sublicensee may assign such Sublicense Agreement without such consent to its successor in interest pursuant to the acquisition or merger of or sale of all or substantially all of the assets of such Sublicensee. In addition, except as expressly provided herein, the Sublicensee shall not transfer or otherwise dispose of any or all of the rights, duties or obligations granted to it under the Sublicense Agreement (but provided that Sublicensee may use third party contractors to perform routine functions on its behalf in the development or commercialization of Products or Licensee Owned Improvement Products).

2. The Sublicensee shall acknowledge all ownership of the sublicensed Technology, Improvements, and Licensed Patents as set out in Article 2.1 of the License Agreement (in this Schedule "**C**", the "**License Agreement**").

3. The Sublicensee shall acknowledge that UBC has the right to use the Technology, Improvements (other than Licensee Owned Improvements), and Licensed Patents without charge in any manner whatsoever for research, scholarly publication, educational and other non-commercial uses in all fields of use in accordance with the terms of the License Agreement.

4. Publication and Confidentiality

   (a) The Sublicensee shall keep and use all of UBC's Confidential Information in confidence and will not, without UBC's prior written consent, disclose any of UBC's Confidential Information to any person or entity, except those of the Sublicensee's directors, officers, employees, technical consultants and professional advisors who require said Confidential Information in connection with the Sublicensee performing its obligations or exercising its rights under the Sublicense Agreement. The Sublicensee shall also covenant and agree that it will initiate and maintain an appropriate internal program limiting the internal distribution of UBC's Confidential Information to only those directors, officers, employees, technical consultants and professional advisors who require said Confidential Information in connection with the Sublicensee performing its obligations or exercising its rights under the Sublicense Agreement and who are under obligations of confidentiality consistent to those of the License Agreement.

   (b) The Sublicensee shall acknowledge that UBC shall not be restricted from presenting at symposia, national or regional professional meetings, or from publishing in journals or other publications, accounts of its research relating to the Technology and any Improvements (other than Licensee Owned Improvements) in accordance with the terms of the License Agreement.

5. The Sublicensee shall agree not to use UBC's name, trade-marks, service marks, logos, insignia, seal, or designs without the prior written consent of UBC, such consent not to be unreasonably withheld.

6. The Sublicensee shall procure and maintain insurance in accordance with Article 13.4 of the License Agreement.

7. The Sublicensee shall acknowledge and agree that UBC makes no representations, conditions or warranties, either express or implied, with respect to the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products. Without limiting the generality of the foregoing, the Sublicensee shall acknowledge that:

    (i) UBC specifically disclaims any express or implied warranty, condition or representation as to title to the Licensed Patents, Technology or any Improvements or that anything made, used, sold or otherwise disposed of under the license granted in the Sublicense Agreement will not infringe the patents, copyrights, trade-marks, industrial designs or other intellectual property rights of any third parties, including any patents, copyrights, trade-marks, industrial design or other intellectual property rights owned, in whole or in part, by UBC, or licensed by UBC to any third parties;

    (ii) UBC makes no express or implied warranty, condition or representation that the Licensee or Sublicensee has, or will have the freedom to operate or practice the Licensed Patents, Technology or any Improvements, or the freedom to make, have made, use, sell or otherwise dispose of Products or Licensee Owned Improvement Products; or

    (iii) UBC is under no obligation to bring, prosecute or defend actions or suits against third parties for infringement of patents, copyrights, trade-marks, industrial designs or other intellectual property or contractual rights.

8. The Sublicensee shall acknowledge and agree that UBC will not be liable for any loss, whether direct, consequential, incidental or special, which the Sublicensee or any other third parties suffer, arising from any defect, error or fault of the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products, or their failure to perform, even if UBC is aware of the possibility of the defect, error, fault or failure. The Sublicensee will also acknowledge that it has been advised to undertake its own due diligence regarding the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products, and that UBC is under no obligation to bring, prosecute or defend actions or suits against third parties for infringement of patents, copyrights, trade-marks, industrial designs or other intellectual property or contractual rights in relation to the Licensed Patents, Technology, Improvements, Products or Licensee Owned Improvement Products.

9. The Sublicensee shall indemnify holds harmless and defends UBC and its Board of Governors, officers, employees, faculty, students, invitees and agents against any and all third party claims against such indemnitiees (including all associated legal fees and disbursements actually incurred) arising out of the exercise by Sublicensee of any rights under the Sublicense Agreement, including without limitation against any damages or losses, consequential or otherwise, resulting from such third party claims based in any manner at all from or out of the use of the Licensed Patents, Technology, Improvements,

Products or Licensee Owned Improvement Products by the Sublicensee or its customers or end-users.

10. The Sublicensee shall agree to limit its claims against UBC, whether under the express or implied terms of the Sublicense Agreement or the License Agreement, in tort (including negligence) or at common law, for any loss or damage suffered by the Sublicensee, whether direct, indirect or special, or any other similar damage that may arise or does arise from any actions or inactions, defaults or breaches by UBC, its Board of Governors, officers, employees, faculty, students or agents, to **[*]**.

11. The Sublicensee shall also acknowledge and agree that UBC will not be liable for consequential or incidental damages, including any consequential or incidental damages arising from any breach or breaches of the Sublicense Agreement or the License Agreement.

12. The Sublicense shall include termination provisions such that the Sublicense Agreement shall terminate:

    (a) upon termination of the License Agreement between UBC and the Licensee;

    (b) automatically if any proceeding under any applicable bankruptcy or insolvency laws, or any other legislation of similar purport, are started by or against the Sublicensee;

    (c) if the Sublicensee ceases to carry on business, or any resolution is passed or order made or other steps taken for the winding up, liquidation or other termination of the existence of the Sublicensee;

    (d) if the Sublicensee is in material default under any term of the Sublicense Agreement and:

        (i) if such default is reasonably curable within thirty (30) days after receipt of notice of such default and such default is not cured within thirty (30) days after receipt of written notice thereof, or

        (ii) if such default is not reasonably curable within thirty (30) days after receipt of written notice thereof, and such default is not cured within such further reasonable period of time as may be necessary for the curing of such default;

    (e) if the Sublicensee fails to procure or maintain insurance as required under the Sublicense Agreement.

13. The Sublicensee shall cease to use the Licensed Patents, Technology, Improvements in any manner whatsoever and shall cease to manufacture Products within five days from the effective date of termination of the Sublicense Agreement. If the Sublicense Agreement is terminated due to a

default of the Licensee, then the Sublicensee will be entitled to dispose of all previously made Products, but no more, and the terms of the Sublicense Agreement shall continue to be applicable during the period that the Sublicensee carries out such disposition.

14. The Sublicensee shall maintain separate accounts and records of all business done in connection with the Licensed Patents, Technology, Improvements, Products and Licensee Owned Improvement Products. These accounts and records will be in sufficient detail to enable proper returns to be made by the Licensee to UBC under the License Agreement.

CONFIDENTIAL

SCHEDULE "D"

Payment Report for the Period dd/mm/yy to dd/mm/yy

Instructions for Completing this Report

Please fill out each section in full, identifying in the Royalty Summary Table the unit sales and geographical sales areas. If the licence with UBC involves several product lines, please prepare a separate Summary Table for each product line. For licences involving one or more sublicenses, please prepare an additional report for the Revenue received by each Sublicensee.

PLEASE NOTE: An interest rate of [*] per annum, calculated annually not in advance will be assessed against all payments made after the due date.

Licensee (or sublicensee)	NewLink Genetics Corporation	Agreement #	UBC ID #

UBC Technology

Report Type (check one and complete as appropriate)

Single Product Line o Product Line Trade Name

Multiple Products o Page Of Product Line Trade Name

Sublicense Report o Page Of

Payments this Quarter (please complete separate tables for multiple product lines) Royalties on Product Sales

Country	Units Sold	Unit Price (domestic currency)	Gross sales	Less Allowances *	Net Sales	Royalty Rate	Conversion Rate (to Canadian $)	Period Royalty Amount (Canadian $) This yr	Period Royalty Amount (Canadian $) Last yr
Canada									
US									
Europe (specify countries)									
Other									
							Total Product Royalties		

Additional Payments (complete all that apply)

Minimum Royalty Fee	o	Amount	
Milestone Payment	o	Amount	
Annual Licence Maintenance Fee	o	Amount	
	o		This Year / Last Year
	o	Total Payments for Period	

*Please indicate the reasons for returns or other allowances, if significant. Please note any unusual occurrences that affected royalty amounts during the period.

Prepared by **Date** Dd/mm/yy Phone

I (print name), (title) hereby certify the foregoing information as true and correct.

Signature Date Signed

CONFIDENTIAL

SCHEDULE "E"

UBC License Agreement Annual Report

The information to be completed below shall constitute the annual report required pursuant to the UBC License Agreement. Any information or documents provided by the Licensee in this report shall not be interpreted as affecting the express rights and obligations of the Licensee contained in the License Agreement. This report is in addition to the Payment Report to accompany each royalty payment.

Date of Report: Person Preparing This Report:

Name of Licensee: UBC File Number:

Jurisdiction of Corporation: Head Office Address:

Contact Person for Company

Licensed Technology:

Telephone Number: E-mail Address:

1. Please provide a brief report on the status of development of the UBC Technology, progress on creating a commercial Product or Licensee Owned Improvement Product, or subsequent marketing of the Product or Licensee Owned Improvement Product as appropriate.

2. Has the Licensee filed any patent applications for modifications or improvements relating to the original UBC Technology?

3. Has the Licensee become aware of any potential 3rd party infringing on the UBC patents or related intellectual property? If so please provide details and outline what the Licensee is doing about this.

4. Has the Licensee met any milestone or performance objectives in the past year as set forth in the license agreement? Please outline the past year's accomplishments.

5. Does the Licensee expect to meet any milestone or performance objective in the coming year as set forth in the license agreement? If so please provide details.

6. If applicable, has the Licensee granted sublicenses to 3rd parties and if so have copies of the sublicense agreement been provided to the Technology Manager at UBC? If not, please enclose a copy of each sublicense agreement.

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7. Has the licensee made any sales in the last 12 months? Yes o No o
   If so please submit a completed Royalty Payment Report.

   a) Date of sales of Products or Licensee Owned Improvement Products utilizing the Technology;

   b) Date of any clinical trials.

8. Does your company have public liability insurance?

9. Please provide the Licensee's estimate or projection of gross sales revenue for products based on the UBC Technology for the next 12 months by licensee and any sub-licensee.

10. Is there any other information relating to this License that you think we should be aware of? Please summarize them below or contact us directly.

Prepared by **Date** Dd/mm/yy Phone

I (print name), (title) hereby certify the foregoing information as true and correct.

Signature Date Signed

Once completed, please submit this report to:

Managing Director c/o Licensing Compliance Officer
University — Industry Liaison Office
#103 — 6190 Agronomy Road,
Vancouver, BC
V6T 1Z3

SCHEDULE "F"

ADDRESS FOR NOTICES & PAYMENT INSTRUCTIONS

1. The address for delivery of notices to UBC is:

The Director
University — Industry Liaison Office
University of British Columbia
#103 — 6190 Agronomy Road
Vancouver, British Columbia
V6T 1Z3
Telephone: (604) 822-8580
Fax: (604) 822-8589

2. Payment of all amounts due to UBC under the terms of this license may be made as follows:

a) by cheque made payable to "The University of British Columbia" delivered to UBC at the above address; or

b) by wire transfer in accordance with the instructions set out below:

Note: Please ensure ALL of the information is provided for efficient receipt of wire payments:

For CAD $ Deposits via wire (General:)

Pay Via: [*]
Pay to: [*]
Bank Address:
[*]

For Account: [*]
Beneficiary: [*]
Reference: [*]
Phone: [*]
Re: [*]
For **Royalties [*]**
For **Patent Fees [*]**
Dept Name: [*]

For USD Deposits via wire:

Pay Via: [*]
Pay to: [*]
Bank Address:
[*]

For Account: [*]
Beneficiary: [*]
Reference: [*]
Phone: [*]
Re: [*]
For **Royalties [*]**
For **Patent Fees [*]**
Dept Name: [*]
Cover/Reimbursement: [*]
Receiving Bank: [*]
Beneficiary Bank: [*]

Exhibit 10.36

LICENSE AGREEMENT

BETWEEN

NEWLINK GENETICS

AND

DREXEL UNIVERSITY

EFFECTIVE AS OF

OCTOBER 13th, 2004

LICENSE AGREEMENT

This License Agreement (this "Agreement") is made on October, 13th, 2004, by and between Drexel University, a Pennsylvania nonprofit corporation, with offices located at 3201 Arch Street, Suite 100, Philadelphia, Pennsylvania 19104 ("DREXEL"), and NewLink Genetics Corporation, a Delaware for-profit corporation ("LICENSEE"), with its principal offices at Iowa State University Research Park, 2901 South Loop Drive, Suite 3900. This Agreement is effective as of October, 13th, 2004 (the "Effective Date").

BACKGROUND

1. DREXEL owns certain intellectual property developed by Dr. Uri Galili of DREXEL relating to Compositions and methods for vaccines comprising .alpha.-galactosyl epitopes, as described more fully in Attachment 1;

2. DREXEL owns the United States letters patent and/or applications therefore listed in Attachment 1 to this Agreement relating to the intellectual property developed by Drs. Uri Galili and Patricia M. Repik as described above;

3. LICENSEE desires to obtain the exclusive right and license to use and exploit the intellectual property developed by Drs. Uri Galili and Patricia M. Repik described in Attachment 1.

4. DREXEL has determined that the exploitation of the intellectual property developed by Drs. Uri Galili and Patricia M. Repik is in the best interest of DREXEL and is consistent with its educational and research missions and goals.

NOW, THEREFORE, in consideration of the promises and covenants contained in this Agreement and intending to be legally bound, the parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1. "Affiliate" means any legal entity directly or indirectly controlling, controlled by or under common control with LICENSEE that has executed (a) this Agreement or (b) a written joiner agreement, in a form satisfactory to DREXEL, agreeing to be bound by all of the terms and conditions of this Agreement as if such Affiliate were an original party to this Agreement. For purposes of this Agreement, "control" means the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting securities of a legal entity, or the right to receive more than fifty percent (50%) of the profits or earnings of a legal entity, or the right to control the policy decisions of a legal entity.

1.2. "Agreement" shall have the meaning given in the first paragraph hereof.

1.3. "Calendar Quarter" means each three-month period, or any portion thereof, beginning on January 1, April 1, July 1 and October 1.

1.4. "Confidential Information" means and includes all technical information, inventions, developments, discoveries, software, know-how, methods, techniques, formulae, data, processes and other proprietary ideas, whether or not patentable or copyrightable, regardless whether DREXEL identifies such information as confidential or proprietary at the time it is delivered or communicated to LICENSEE.

1.5. "Default" shall have the meaning given in Section 5.3

1.6. "Development Plan" means a plan for the development and/or marketing of the Patent Rights and Technical Information that demonstrates LICENSEE's capability to bring the Patent Rights and Technical Information to practical application and is more fully set forth in Attachment 2.

1.7. "Effective Date" shall have the meaning given in the preamble hereof.

1.8. "Fair Market Value" means the cash consideration that LICENSEE or its Sublicensee would realize from an unaffiliated, unrelated buyer in an arm's length sale of an identical item sold in the same quantity and at the same time and place of the transaction.

1.9. “Indemnified Party” shall have the meaning given in Section 8.2.

1.10. “Field of Use” means Compositions and methods for vaccines comprising .alpha.-galactosyl epitopes for diagnosis and treatment of cancer, viral and other infectious diseases.

1.11. “Liability” and “Liabilities” shall have the meaning given in Section 8.2.

1.12. “License” shall mean the license granted by DREXEL to LICENSEE pursuant to Section 2.1.

1.13. “Licensed Product(s)” means products that are made, made for, used or sold by LICENSEE or any Sublicensees and that: (a) in the absence of this Agreement would infringe at least one claim of Patent Rights; (b) use a process or machine covered by a claim of Patent Rights; or (c) use, at least in part, any Technical Information.

1.14. “LICENSEE” shall have the meaning given in the first paragraph of this Agreement.

1.15. “Net Sales” means the consideration or Fair Market Value attributable to the Sale of any Licensed Product(s), less qualifying costs directly attributable to such Sale and actually

identified on the invoice and borne by LICENSEE or its Sublicensee. Such qualifying costs shall be limited to the following:

1.15.1 Discounts, in amounts customary in the trade, for quantity purchases, for prompt payments and for wholesalers and distributors;

1.15.2 Credits or refunds, not exceeding the original invoice amount, for claims or returns;

1.15.3 Prepaid outbound transportation expenses and transportation insurance premiums; and

1.15.4 Sales and use taxes and other fees imposed by a governmental agency.

1.16. “Patent Rights” means all patent rights represented by or issuing from the United States or foreign patents listed in Attachment 1 or the patents issuing from the United States or foreign patent applications listed in Attachment 1, and their foreign counterparts and extensions, including continuation, divisional and re-issue applications and continuation-in-part applications.

1.17. “Sale” means any bona fide transaction for which consideration is received or expected for the sale, use, lease, transfer or other disposition of Licensed Product(s) excluding any sale, use, lease, transfer or other disposition to a Sublicensee unless such Sublicensee is an end user. A Sale of Licensed Product(s) shall be deemed completed at the time LICENSEE or its Sublicensee invoices, ships, or receives payment for such Licensed Product(s), whichever occurs first. Sale shall not include the non-compensated use, transfer or other disposition of Licensed Product for research, development or clinical trial purposes.

1.18. “Sell Off Right” shall have the meaning given in Section 5.8.

1.19. “Sublicense” shall have the meaning given in Section 2.4.1.

1.20. “Sublicense Assignment” shall have the meaning given in Section 2.4.2.

1.21. “Sublicensee” shall have the meaning given in Section 2.4.1.

1.22. “Technical Information” means all the information contained in the patents and the patent applications listed in Attachment 1 (other than the information referenced from patents and publications cited in such patents and patent applications) and any other technical information disclosed or referenced in Attachment 1, in each case that is necessary or useful for practicing the invention(s) covered by Patent Rights.

1.23. “Transaction Documents” means this Agreement.

1.24. “Trigger Event” means any of the following:

1.24.1 If LICENSEE becomes insolvent, bankrupt or generally fails to pay its debts as such debts become due; is adjudicated insolvent or bankrupt; admits in writing its inability to pay its debts; or shall suffer a custodian, receiver or trustee for it or substantially all of its property to be appointed and, if appointed without its consent, not be discharged within thirty (30) days; makes an Assignment for the benefit of creditors; or suffers proceedings under any law related to bankruptcy, insolvency, liquidation or the reorganization, readjustment or the release of debtors to be instituted against it and, if contested by it, not dismissed or stayed within ten (10) days;

1.24.2 If proceedings under any law related to bankruptcy, insolvency, liquidation, or the reorganization, readjustment or the release of debtors are instituted or commenced by LICENSEE;

1.24.3 If LICENSEE shall by any act or failure to act indicate its consent to, approval of or acquiescence in any of the proceedings described in Sections 1.24.1 or 1.24.2; or [*NOTE: The bankruptcy of a Sublicensee or an Affiliate may have no effect whatsoever on NewLink’s ability to perform its obligations tinder this Agreement. Only NewLink’s own bankruptcy/non-performance is an appropriate termination trigger*.]

1.24.4 If a Sublicensee or Affiliate experiences the circumstances described in 1.24.1, 1.24.2 or 1.24.3 and the LICENSEE fails to terminate the Sublicense or provide adequate assurances to DREXEL that LICENSEE will cover all royalty obligations that would arise under such Sublicensee.

ARTICLE 2

LICENSE GRANT

2.1 License Grant. DREXEL grants to LICENSEE and its Affiliates for the term of this Agreement an exclusive, world-wide license under the Patent Rights to make, have made, use, import, sell and offer for sale Licensed Product(s) in the Field of Use, except that to the extent that any Affiliate exercises any rights granted by DREXEL hereunder, LICENSEE remains primarily liable to DREXEL for the duties and obligations of any Affiliate hereunder, and any act or omission of an Affiliate would be deemed to be a breach by LICENSEE of this Agreement. DREXEL grants to LICENSEE only the qualified right to grant sublicenses as more fully described in Section 2.4. No other rights or licenses are granted.

2.2 Exclusivity. The License is exclusive, except that DREXEL may use and permit other nonprofit organizations to use the Patent Rights and the Technical Information for educational and non-commercial research purposes.

2.3 U.S. Government Rights. LICENSEE or its Affiliates acknowledge that pursuant to Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, the United States

government retains certain rights in intellectual property funded in whole or part under any contract, grant or similar agreement with a Federal agency. Pursuant to these laws, the government may impose certain requirements regarding such intellectual property, including but not limited to the requirement that products resulting from such intellectual property sold in the United States must be substantially manufactured in the United States. The License is expressly subject to all applicable United States government rights as provided in the above-mentioned laws and any regulations issued under those laws, as those laws or regulations may be amended from time to time.

2.4 Sublicense Conditions. The right to sublicense granted to LICENSEE under Section 2.1 is subject to the following conditions:

2.4.1 LICENSEE may sublicense the rights granted in this Agreement by written sublicense agreement in a form acceptable to DREXEL, which form shall (a) prohibit the sublicensee ("Sublicensee") from further sublicensing without DREXEL's prior consent and (b) require that the Sublicensee be subject to the terms and conditions of the license granted to LICENSEE under this Agreement (each, a "Sublicense").

2.4.2 Within thirty (30) days after LICENSEE enters into any Sublicense LICENSEE must deliver to DREXEL a complete copy of the Sublicense written in the English language (DREXEL's receipt of the Sublicense shall not constitute an approval of the Sublicense or a waiver of any of DREXEL's rights or LICENSEE's obligations under this Agreement).

2.4.3 In the event of a default by LICENSEE under Section 5.3 hereunder, all payments then or thereafter due to LICENSEE from each of its Sublicensees shall, upon notice from DREXEL to any such Sublicensee, become owed directly to DREXEL for the account of LICENSEE; provided that DREXEL shall remit to LICENSEE the amount by which such payments in the aggregate exceed the total amount owed by LICENSEE to DREXEL. If this Agreement is terminated, DREXEL has the right to accept as successors to LICENSEE such consent not to be unreasonably withheld or delayed, existing Sublicensees in good standing at the date of termination, provided that the Sublicensees consent in writing to be bound by all the terms and conditions of this Agreement.

2.4.4 Even if LICENSEE enters into Sublicenses, LICENSEE remains primarily liable to DREXEL for all of LICENSEE's duties and obligations contained in this Agreement. LICENSEE shall diligently enforce the terms and conditions of each Sublicense, and if any Sublicensee commits an act or omission that would be a breach of this Agreement if performed by LICENSEE, LICENSEE shall exercise all rights and remedies it has under the Sublicense.

ARTICLE 3

FEES AND ROYALTIES

3.1 License Initiation Fee and Royalties.

3.1.1 In partial consideration of the License, LICENSEE shall pay to DREXEL on the Effective Date of this Agreement, a non-refundable license initiation fee of **[*]**.

3.1.2 In partial consideration of the License, LICENSEE shall pay to DREXEL on the Effective Date of this Agreement, a non-refundable fee of **[*]** for past patent costs.

3.1.3 In further consideration of the exclusive License granted to LICENSEE, LICENSEE shall pay to DREXEL the below listed royalties based on the Net Sales of Licensed Products made, made for, used or sold by LICENSEE, its Affiliates and/or Sublicensees.

[*] of Net Sales for each Licensed Product that is a **[*]** on Sales in **[*]***

[*] of Net Sales for each Licensed Product that is a **[*]** on Sales in **[*]***

[*] of Net Sales for each Licensed Product that is an **[*]** on Sales in **[*]***

	*Reduced if combined with other technologies (defined in Stacking royalty below).
Stacking royalty (if combined with other technologies)	**[*]** of Net Sales for each Licensed Product that is an **[*]** on Sales in **[*]**.
	[*] of Net Sales for each Licensed Product that is an **[*]** on Sales in **[*]**.
	[*] of Net Sales for each Licensed Product that is an **[*]** on Sales in **[*]**.

3.1.4 In further consideration of the exclusive License granted to LICENSEE, LICENSEE shall pay to DREXEL the following milestone payments:

3.1.4.1 Upon **[*]** for any Licensed Product, the sum of: **[*]** on each **[*]** for **[*]**. Capped at **[*]**.

3.1.4.2 Upon **[*]** for any Licensed Product, the sum of: **[*]** on each **[*]** for the United States. Capped at **[*]**.

3.1.4.3 Upon **[*]** for any Licensed Product, the sum of: **[*]** on each **[*]** for **[*]**.

3.1.4.4 Upon **[*]** for any Licensed Product, the sum of: **[*]** on each **[*]** for the United States.

3.1.5 LICENSEE shall pay to DREXEL **[*]** of any Sublicense initiation fee or other such consideration paid by each Sublicensee of this Agreement, other than up front sums received: (i) for the purchase of an equity interest in LICENSEE at Fair Market Value;

(ii) for research and development work performed by or for LICENSEE not to exceed Fair Market Value; or (iii) for purchase of a supply of Licensed Product at Fair Market Value. Any non-cash consideration received by the LICENSEE from such Sublicensees shall be valued at its Fair Market Value as of the date of receipt.

3.1.6 Net Sales of any Licensed Product shall not be subject to more than one assessment of the scheduled royalty; such assessment shall be the highest applicable royalty.

3.2 Diligence and Maintenance Fees.

3.2.1 LICENSEE shall use its commercially reasonable efforts to **[*]**. Notwithstanding the above, LICENSEE (a) **[*]** within 5 years of the Effective Date and/or (b) shall demonstrate on the 5th anniversary of the Effective Date and on each anniversary thereafter that LICENSEE has **[*]** to make **[[*]**.

3.2.2 LICENSEE shall provide to DREXEL, on the Effective Date and on each anniversary thereafter, written progress reports, setting forth in such detail as DREXEL may reasonably request: (a) the progress of the development, evaluation, testing and commercialization of each Licensed Product; and (b) the LICENSEE'S strategic alliances with industry counterparts that, in the best judgment of the LICENSEE, represent effective and beneficial business relationships. LICENSEE shall also notify DREXEL in writing within thirty (30) days after the first commercial sale of each Licensed Product.

3.2.3 LICENSEE shall provide to DREXEL, at least as frequently as they are distributed to the Board of Directors and/or management of LICENSEE copies of: all Board and managerial reports that relate to the Technical Information, Patent Rights and Licensed Products.

3.2.4 LICENSEE shall pay to DREXEL a non-refundable annual license maintenance fee of **[*]** due and payable on the first anniversary of the Effective Date. Thereafter, the LICENSEE shall pay to DREXEL a non-refundable annual license maintenance

fee of **[*]** due and payable on each anniversary of the Effective Date until the end of this Agreement.

3.3 Royalty Reports and Records.

3.3.1 Prior to the commencement of Sales of Licensed Products, LICENSEE shall deliver to DREXEL within forty-five days after the end of LICENSEE's fiscal year a statement signed by the Chief Financial Officer indicating that there have been no Sales of Licensed Product for such fiscal year. Once that Sales of Licensed Products are realized, LICENSEE shall deliver to DREXEL within forty-five (45) days after the end of each Calendar Quarter a written report, certified by the chief financial officer of LICENSEE, setting forth the calculation of the royalties due to DREXEL for such Calendar Quarter, including, without limitation:

3.3.1.1 Number of Licensed Products involved in Sales, listed by country;

3.3.1.2 Gross consideration for Sales of Licensed Products, including all amounts invoiced, billed, or received;

3.3.1.3 Qualifying costs, as defined in Section 1.15, listed by category of cost;

3.3.1.4 Net Sales of Licensed Products listed by country;

3.3.1.5 Royalties owed to DREXEL, listed by category, including without limitation earned, Sublicensee derived, and minimum royalty categories; and

3.3.2 LICENSEE shall pay the royalties due under Sections 3.1 and 3.3 to DREXEL within thirty (30) days following the last day of the Calendar Quarter in which the royalties accrue. LICENSEE shall send DREXEL with such royalties the report described in Section 3.3.1.

3.3.3 LICENSEE shall maintain and cause its Sublicensees to maintain, complete and accurate books and records that enable the royalties payable under this Agreement to be verified. The records for each Calendar Quarter shall be maintained for three (3) years after the submission of each report under Article 3. Upon reasonable prior notice to LICENSEE, LICENSEE shall provide an independent auditor selected by DREXEL and reasonably acceptable to LICENSEE with access to all books and records relating to the Sales of Licensed Products by LICENSEE and its Sublicensees to conduct a review or audit of those books and records. The auditor shall disclose to DREXEL the findings of the accuracy of any report made or payment submitted by LICENSEE during the audited period, but shall not disclose to any of DREXEL any confidential information of LICENSEE not necessary for such purpose. Access to LICENSEE's books and records shall be made available no more than once each Calendar Year, during normal business hours, and during each of three (3) years after the

expiration or termination of this Agreement. If DREXEL determines that LICENSEE has underpaid any royalty due by five percent (5%) or more, then LICENSEE shall pay to DREXEL promptly the costs and expenses of DREXEL and its accountants in connection with their review or audit, in addition to such underpayment.

3.4 Currency, Place of Payment, Interest, Payment of Expenses.

3.4.1 All dollar amounts referred to in this Agreement are expressed in United States dollars. All payments to DREXEL under this Agreement shall be made in United States dollars by check payable to "Drexel University". If LICENSEE receives revenues from Sales of Licensed Products in currency other than United States dollars, then revenues shall be converted into United States dollars at the conversion rate for the foreign currency as published in the eastern edition of The Wall Street Journal as of the last business day of the applicable Calendar Quarter.

3.4.2 Amounts that are not paid when due shall accrue interest from the due date until paid, at a rate equal to **[*]** per month or part thereof (or the maximum allowed by law, if less).

ARTICLE 4

CONFIDENTIALITY

4.1 Non-Disclosure by LICENSEE. LICENSEE shall maintain in confidence and not disclose to any third party any Confidential Information of DREXEL. LICENSEE shall ensure that its employees have access to Confidential Information only on a need-to-know basis and are obligated in writing to abide by LICENSEE's obligations under this Agreement. The foregoing obligation shall not apply to:

4.1.1 Information that is known to LICENSEE prior to the time of disclosure or independently developed by LICENSEE without use of or reference to the Confidential Information, in each case, to the extent evidenced by written records promptly disclosed to DREXEL;

4.1.2 Information disclosed to LICENSEE by a third party that has aright to make such disclosure;

4.1.3 Information that is or becomes patented, published or otherwise part of the public domain as a result of acts by DREXEL or a third person obtaining such information as a matter of right; or

4.1.4 Information that is required to be disclosed by order of United States governmental authority or a court of competent jurisdiction; provided that LICENSEE shall use best efforts to obtain confidential treatment of such information as permitted by the agency or court.

4.2 Limited Non-Disclosure by DREXEL. DREXEL shall not be obligated to accept any confidential information from LICENSEE except for the reports required in Sections 3.2 and 3.3. DREXEL shall not disclose those reports to any third party other than DREXEL's outside advisors who are bound by obligations of confidentiality (subject to exceptions similar to these applicable to LICENSEE under Section 4.1). DREXEL bears no institutional responsibility for maintaining the confidentiality of any other information of LICENSEE.

ARTICLE 5

TERM AND TERMINATION

5.1 Term. This Agreement, unless sooner terminated as provided in this Agreement, terminates upon expiration of the last to expire or become abandoned of the Patent Rights.

5.2 Termination by LICENSEE. LICENSEE may, upon sixty (60) days written notice to DREXEL, terminate this Agreement by doing all of the following:

5.2.1 Ceasing to make, have made, use, import, sell and offer for sale all Licensed Products;

5.2.2 Terminating all Sublicenses, and causing all Sublicensees and Affiliates to cease making, having made, using, importing, selling and offering for sale all Licensed Products; and

5.2.3 Paying all monies owed to DREXEL under this Agreement, up to the date of termination of this Agreement.

5.3 Termination by DREXEL. DREXEL may terminate this Agreement if any of the following events of default ("Default") occur:

5.3.1 LICENSEE is more than thirty (60) days late in paying to DREXEL royalties, expenses, or any other monies due under this Agreement and LICENSEE does not pay DREXEL in full within ten (10) days after written notice of the failure to pay.

5.3.2 LICENSEE experiences a Trigger Event; or

5.3.3 LICENSEE breaches this Agreement (other than a breach solely under Sections 5.3.1 or 5.3.2) and does not cure the breach within sixty (60) days after written notice of the breach.

5.4 Effect of Termination. In the event of a termination under Sections 5.1 or 5.3 hereof, all duties of DREXEL and all rights (but not duties) of LICENSEE and any Affiliate and/or Sublieensee under this Agreement shall immediately terminate without the necessity of any action being taken either by DREXEL or by LICENSEE or any Affiliate or Sublicensee. Upon and after any termination of this Agreement, LICENSEE and any Affiliate and/or

Sublicensee shall refrain from further manufacture, sale, marketing, importation and/or distribution of Licensed Product(s), except as provided in this Article 5.

5.5 Return of Confidential Information. Upon termination of this Agreement, LICENSEE and any Affiliate and/or Sublicensee shall, at DREXEL's request, return to DREXEL all Confidential Information.

5.6 Inventories. Upon termination of this Agreement, LICENSEE shall cause physical inventories to be taken immediately of: (a) all completed Licensed Product(s) on hand under the control of LICENSEE or any Affiliate or Sublicensee; and (b) such Licensed Product(s) as are in the process of manufacture and component parts thereof as of the date of termination of this Agreement, which inventories shall be reduced to writing. LICENSEE shall deliver copies of such written inventories, verified by an officer of LICENSEE forthwith to DREXEL. DREXEL shall have 45 days after receipt of such verified inventories within which to challenge the inventory and request an audit. Upon five days written notice to LICENSEE, DREXEL and its agents shall be given access during business hours to the premises of LICENSEE, its Affiliates and/or Sublicensees for the purpose of conducting an audit. Upon the termination of this Agreement, LICENSEE shall, at its own expense forthwith remove, efface or destroy all references to DREXEL from all advertising or other materials used in the promotion of LICENSEE's business or the business of any Affiliate or Sublicensee and LICENSEE and any Affiliate and/or Sublicensee shall not thereafter represent in any manner that it has rights in or to the Patent Rights or Licensed Product(s).

5.7 Sell Off Rights. Notwithstanding the foregoing, if this Agreement terminates other than pursuant to Section 5.1, 5,3.1 or 5.3.2, LICENSEE and its Affiliates shall have a period of six (6) months to sell off its inventory of Licensed Product(s) existing on the date of termination of this Agreement and shall pay royalties to DREXEL with respect to such Licensed Product(s) within thirty (30) days following the expiration of such six-month period ("Sell Off Right").

5.8 Survival. LICENSEE's obligation to pay all monies owed accruing under this Agreement shall survive termination of this Agreement. In addition, the provisions of Article 4 - Confidentiality, Article 5 - Term and Termination, Article 8 - Disclaimer of Warranties; Indemnification, Article 9 Use of DREXEL's Name; Independent Contractor and Article 10 - Additional Provisions shall survive such termination.

ARTICLE 6

PATENT MAINTENANCE AND REIMBURSEMENT

DREXEL retains control over the prosecution and maintenance of Patent Rights. Notwithstanding the foregoing, DREXEL shall obtain LICENSEE's consent prior to filing any

additional patent application(s) in any country not identified on Attachment 1. LICENSEE shall reimburse DREXEL for all reasonable documented attorneys fees, expenses, official fees and other charges incident to the preparation, prosecution and maintenance of Patent Rights within thirty (30) days after LICENSEE's receipt from time to time of invoices for such fees, expenses and charges. DREXEL shall seek reasonable claims to protect the Patent Rights consistent with DREXEL's overall patent strategy. DREXEL's patent counsel shall keep LICENSEE advised as to the status of the Patent Rights by providing LICENSEE, in a timely manner at least thirty (30) days prior to their due date, with copies of all official documents and correspondence relating to the filing, prosecution, maintenance, and validity of the Patent Rights. LICENSEE shall have fifteen (15) calendar days to review and comment on patent-related documents prior to the filing of such documents and correspondence. DREXEL shall not abandon prosecution of any patent application or maintenance of any patent with the Patent Rights without first notifying LICENSEE sixty (60) days prior to any bar date, of DREXEL's intention and reasons therefore, and providing LICENSEE with reasonable opportunity to assume responsibility for prosecution and maintenance of such patents and patent applications. However, with respect to the issued patents, DREXEL'S patent counsel will send invoices directly to LICENSEE for patent fees and taxes related to maintenance of such patents, with copies to DREXEL, at least 60 days prior to a deadline. LICENSEE shall pay such invoices directly to such patent counsel at least 30 days prior to the deadline, with a copy of correspondence and payment to DREXEL.

ARTICLE 7

INFRINGEMENT AND LITIGATION

7.1 Notification of Infringement. DREXEL and LICENSEE are responsible for notifying each other promptly of any infringement of Patent Rights which may come to their attention. DREXEL and LICENSEE shall consult one another in a timely manner concerning any appropriate response to the infringement.

7.2 Prosecution by LICENSEE. LICENSEE may prosecute such infringement at its own expense. LICENSEE shall not settle or compromise any such suit in a manner that imposes any obligations or restrictions on DREXEL or grants any rights to the Technical Information or the Patent Rights, without DREXEL's prior written permission. Except as otherwise provided in Section 7.3, financial recoveries from any such litigation will first be applied to reimburse LICENSEE for its litigation expenditures with additional recoveries being paid to LICENSEE, subject to a royalty due DREXEL based on the provisions of Article 3.

7.3 Intervention by DREXEL. LICENSEE's rights under Section 7.2 are subject to the continuing right of DREXEL to intervene at DREXEL's own expense and join LICENSEE in any claim or suit for infringement of the Patent Rights. Any consideration received by LICENSEE in settlement of any claim or suit shall be shared between DREXEL and LICENSEE in proportion with their share of the litigation expenses in such infringement action.

7.4 Prosecution by DREXEL. If LICENSEE fails to prosecute any infringement, then DREXEL may prosecute such infringement at its own expense. In such event, financial recoveries will be entirely retained by DREXEL.

7.5 Cooperation. In any action to enforce any of the Patent Rights, either party, at the request and expense of the other party shall cooperate to the fullest extent reasonably possible. This provision shall not be construed to require either party to undertake any activities, including legal discovery, at the request of any third party except as may be required by lawful process of a court of competent jurisdiction.

ARTICLE 8

DISCLAIMER OF WARRANTIES; INDEMNIFICATION

8.1 NO WARRANTIES. DREXEL represents and warrants to LICENSEE that: (i) DREXEL has sufficient legal and/or beneficial title under its interest in to the Patent Rights necessary to grant the License; and (ii) it has not granted any right to a third party under the Patent Rights. EXCEPT AS EXPRESSLY PROVIDED HEREIN, THE PATENT RIGHTS, TECHNICAL INFORMATION, LICENSED PRODUCTS AND ALL OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" BASIS, AND DREXEL MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT THERETO. BY WAY OF EXAMPLE BUT NOT OF LIMITATION, DREXEL MAKES NO REPRESENTATIONS OR WARRANTIES: (a) OF COMMERCIAL UTILITY; (b) OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; OR (c) THAT THE USE OF THE PATENT RIGHTS, TECHNICAL INFORMATION, LICENSED PRODUCTS OR ANY TECHNOLOGY LICENSED UNDER THIS AGREEMENT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADE SECRET OR TRADEMARK OR OTHER PROPRIETARY OR PROPERTY RIGHTS OF OTHERS. DREXEL SHALL NOT BE LIABLE TO LICENSEE, LICENSEE'S SUBLICENSEES OR THEIR RESPECTIVE SUCCESSORS OR ASSIGNS OR ANY THIRD PARTY WITH RESPECT TO: ANY CLAIM ARISING FROM USE OF THE PATENT RIGHTS, TECHNICAL INFORMATION, LICENSED PRODUCTS OR ANY TECHNOLOGY LICENSED UNDER THIS AGREEMENT OR FROM THE MANUFACTURE, USE OR SALE OF LICENSED PRODUCTS; OR ANY CLAIM FOR LOSS OF PROFITS, LOSS OR INTERRUPTION OF BUSINESS, OR FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

8.2 Indemnification. LICENSEE shall indemnify, defend and hold harmless DREXEL, its trustees, officers, agents and employees (individually, an "Indemnified Party", and collectively, the "Indemnified Parties"), from and against any and all third party liability, loss, damage, action, claim or expense suffered or incurred by the Indemnified Parties

(including attorneys' fees and expenses) (individually, a "Liability", and collectively, the "Liabilities") that results from or arises out of **[*]**; and (c) the enforcement by an Indemnified Party of this Section 8.2. Without limiting the foregoing, LICENSEE shall defend, indemnify and hold harmless the Indemnified Parties from and against any Liabilities resulting from:

8.2.1 Any product liability or other claim of any kind related to the use by a third party of a Licensed Product that was manufactured, sold or otherwise disposed by LICENSEE, its Affiliates, its assignees, Sublicensees, vendors or other third parties;

8.2.2 A claim by a third party that the Technical Information or Patent Rights or the design, composition, manufacture, use, sale or other disposition of any Licensed Product infringes or violates any patent, copyright, trade secret, trademark or other intellectual property rights of such third party; and

8.2.3 Clinical trials or studies conducted by or on behalf of LICENSEE, its Affiliates, its assignees, Sublicensees or agents relating to the Technical Information, Patent Rights or Licensed Products, including, without limitation, any claim by or on behalf of a human subject of any such clinical trial or study, any claim arising from the procedures specified in any protocol used in any such clinical trial or study, any claim of deviation, authorized or unauthorized, from the protocols of any such clinical trial or study, and any claim resulting from or arising out of the manufacture or quality control by a third party of any substance administered in any clinical trial or study.

8.3 Rights of DREXEL in Liability Action. LICENSEE is not permitted to settle or compromise any claim or action giving rise to Liabilities in a manner that imposes any restrictions or obligations on DREXEL or grants any rights to the Technical Information, Patent Rights or Licensed Products without DREXEL's prior written consent. If LICENSEE fails or declines to assume the defense of any such claim or action within thirty (30) days after notice thereof, then DREXEL may assume the defense of such claim or action for the account and at the risk of LICENSEE, and any Liabilities related thereto shall be conclusively deemed a liability of LICENSEE. The indemnification rights of DREXEL or other Indemnified Party contained herein are in addition to all other rights that such Indemnified Party may have at law or in equity or otherwise.

8.4 Insurance

8.4.1 LICENSEE and any Affiliate shall procure and maintain a policy or policies of comprehensive general liability insurance, including broad form and contractual liability, in a minimum amount of $2,000,000 combined single limit per occurrence and in the aggregate

as respects personal injury, bodily injury and property damage arising out of such party's performance of this Agreement.

8.4.2 LICENSEE and any Affiliate shall, upon commencement of clinical trials involving Licensed Products, procure and maintain a policy or policies of product liability insurance in a minimum amount of $3,000,000 combined single limit per occurrence and in the aggregate as respects bodily injury and property damage arising out of such party's performance of this Agreement.

8.4.3 The policy or policies of insurance described in this Section 8.4 shall be issued by an insurance carrier with an A.M. Best rating of "A-" or better and shall name DREXEL as an additional insured with respect to LICENSEE's performance of this Agreement. LICENSEE and any Affiliate shall provide DREXEL with certificates evidencing the insurance coverage required herein and all subsequent renewals thereof. Such certificates shall provide that the insurance carrier(s) notify DREXEL in writing at least 30 days prior to cancellation or material change in coverage.

8.4.4 DREXEL may periodically review the adequacy of the minimum limits of liability insurance specified in this Section, and DREXEL reserves the right in its reasonable discretion to require LICENSEE and any Affiliate to adjust the liability insurance coverages, but may not require LICENSEE to maintain limits in excess of what is deemed reasonable in the biopharmaceutical industry. The specified minimum insurance amounts do not constitute a limitation on the obligation of LICENSEE and any Affiliate to indemnify DREXEL under this Agreement.

ARTICLE 9

USE OF DREXEL'S NAME

LICENSEE and its Affiliates, employees, Sublicensees and agents shall not use, and LICENSEE shall not permit its Sublicensees to use, DREXEL's name or any adaptation thereof, in any advertising or promotional materials or any DREXEL seal, logotype, trademark, or service mark, or the name, mark, or logotype of any DREXEL representative or organization in any way, without the prior written consent of DREXEL in it sole discretion. Notwithstanding the above, Drexel and LICENSEE will work cooperatively to agree upon language for press releases and public statements.

ARTICLE 10

ADDITIONAL PROVISIONS

10.1 No Agency. Nothing in this Agreement shall be deemed to establish a relationship of principal and agent between DREXEL and LICENSEE or its Affiliates or Sublicensees, nor any of their agents or employees for any purpose whatsoever, nor shall this Agreement be construed as creating any other form of legal association or arrangement which would impose liability upon one party for the act or failure to act of the other party.

10.2 No Assignment. None of LICENSEE, its Affiliates and/or Sublicensees is permitted to assign this Agreement or any part of it, either directly or by merger or other operation of law, without the prior written consent of DREXEL not to be unreasonably withheld or delayed. Any prohibited assignment of this Agreement or the rights hereunder shall be null and void. No assignment relieves LICENSEE, its Affiliates and/or Sublicensees of responsibility for the performance of any accrued obligations that LICENSEE, its Affiliates and/or Sublicensees has prior to such assignment.

10.3 No Waiver. No waiver of any breach or condition of this Agreement shall be deemed to be a waiver of any other subsequent breach or condition, whether of like or different nature.

10.4 Notices. All notices, requests, consents and other communications hereunder shall be in writing and shall be delivered in person or sent overnight delivery by Federal Express or by certified or registered mail, return receipt requested, or telexed in the case of non-U.S. residents, and shall be deemed to have been given when hand delivered, one (1) day after mailing when mailed by overnight courier (e.g. Federal Express or Express Mail) or five (5) days after mailing by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received):

If to DREXEL:

Office of Research
Drexel University
Technology Commercialization
3225 Arch Street, Ground Floor
Philadelphia, Pennsylvania 19104
Attention: Anil Rastogi
Vice President for Special Projects

If to LICENSEE:

Nicholas Vahanian
NewLink Genetics Corporation
2901 South Loop Dr, Suite 3900
Ames, IA 50010

or to such other names or addresses as LICENSEE or DREXEL, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section 10.4.

10.5 Governing Law and Jurisdiction. This Agreement shall be construed and governed in accordance with the laws of the State of Delaware, without giving effect to conflict of law provisions of any jurisdiction. In the event that a party to this Agreement perceives the existence of a dispute with the other party concerning any right or duty provided for herein, the parties will, as soon as practicable, confer in an attempt to resolve the dispute. If the parties are unable to resolve such dispute amicably, then the parties hereby submit to the exclusive jurisdiction of and venue in the state and federal courts located in Delaware with respect to any and all disputes concerning the subject of, or arising out of, this Agreement.

10.6 No Discrimination. DREXEL and LICENSEE, its Affiliates and Sublicensees shall not discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or because he or she is a disabled veteran or a veteran of the Vietnam Era.

10.7 Compliance with Laws. LICENSEE, its Affiliates and Sublicensees shall comply with all prevailing laws, rules and regulations that apply to its activities or obligations under this Agreement. Without limiting the foregoing, it is understood that this Agreement may be subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, articles and information, including the Arms Export Control Act as amended in the Export Administration Act of 1979, and that the parties' obligations are contingent upon compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE, its Affiliates and/or Sublicensees that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. DREXEL neither represents that a license is not required nor that, if required, it will issue.

10.8 Binding Nature of Agreement. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, personal representatives, successors and assigns, except that any assignment by LICENSEE must comply with Section 10.2 to be effective.

10.9 Counterparts, Headings and Exhibits. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The headings used in this Agreement are for convenience only and are not to be considered in construing or interpreting any term or provision of this Agreement. All Schedules and Exhibits hereto are hereby incorporated in this Agreement and made a part hereof.

10.10 Integration and Amendment. This Agreement embodies the entire agreement and understanding among the parties hereto and thereto and supersede all prior agreements and understandings relating to the subject matter hereof or thereof. This Agreement may not be changed, modified, extended or terminated except by written amendment executed by an authorized representative of each party.

10.11 Severability. If any provision of this Agreement shall be held to be illegal, invalid or unenforceable, then such illegality, invalidity or unenforceability shall attach only to such provision and shall not in any manner affect or render illegal, invalid or unenforceable any other provision of this Agreement, and this Agreement shall be carried out as if any such illegal, invalid or unenforceable provision were not contained herein.

10.12 Number of Days. In computing the number of days for purposes of this Agreement, all days shall be counted, including Saturdays, Sundays and holidays; provided that if the final day of any time period falls on a Saturday, Sunday or holiday on which Federal banks are or may elect to be closed, then the final day shall be deemed to be the next day which is not a Saturday, Sunday or such holiday.

IN WITNESS WHEREOF, the parties, intending to be legally bound, have caused this Agreement to be executed by their duly authorized representatives.

DREXEL UNIVERSITY		LICENSEE: NEW LINK GENETICS CORPORATION	
By:	/s/Anil Rastogi	By:	/s/Nicholas Vahanian
Name:	Anil Rastogi, Ph.D.	Name:	Nicholas Vahanian, M.D.
Title:	Vice President for Special Projects	Title:	Chief Medical and Operations Officer
Date:	October 13, 2004	Date:	October 14, 2004

Attachment 1 - List of Patents and Patent Applications

Drexel Patents:

United States	Patent Number: 5,879,675	(issued 3/9/99)
	Patent Number: 6,361,775	(issued 3/26/02)
Canada	Patent Number: **[*]**	
European	Patent Number: **[*]**	
France	Patent Number: **[*]**	
Great Britain	Patent Number: **[*]**	
Italy	Patent Number: **[*]**	
Germany	Patent Number: **[*]**	

Attachment 2 - Development Plan

One of LICENSEE's main technology platforms is the HyperAcute™ family of cancer vaccines which have already entered clinical trials. The first trial based on HyperAcute™ technology was approved for use in human clinical trials in 2003 and a PhaseI/II trial of HyperAcute-Lung for patients with late stage non-small lung cancer is being conducted at the National Cancer Institute in Bethesda, Maryland. The second drug, HyperAcute™-breast was approved by the FDA for human clinical trials in late 2003 and a Phase I/II trial of this vaccine in women with recurrent or refractory breast cancer is currently screening patients in central Iowa locations. In 2004-2005, LICENSEE will submit two additional Investigational New Drug Applications for clinical trials of HyperAcute™-based drugs for the treatment of prostate cancer and melanoma, with the intention to open the trials for patients during 2005.

Furthermore, LICENSEE's intends to expand its drug portfolio to antiviral vaccines based on the use of a-galactosylated viral antigens. In particular, LICENSEE intends to apply this technology primarily for the development of **[*]**, but it may also investigate the implementation of this technology for **[*]** and potentially to treat or prevent **[*]**. Development of this technology has to evolve through several steps that first involve conceptualization of the experiments, and then in vitro and animal preclinical testing, human clinical trials and commercial production and development.

Due to the theoretical and practical difficulties that an **[*]** has shown in previous clinical trials it is not possible to make a prediction of which would be the best way for implementation of this technology for the development of an effective vaccine. Therefore, several strategies are under consideration, which include the following antigenic preparations for the induction of cellular cytotoxicity and **[*]** antibodies:

[*]

The above mentioned strategies are purely theoretical at this point, and LICENSEE does not give any warranty that their implementation will be successful for prevention or treatment of **[*]**. Similar embodiments of these ideas can be adapted for the preparation of other antiviral vaccines.

From the commercial standpoint, we intend to develop and market the above mentioned cancer and viral vaccines in the United States and also to expand these operations to **[*]**.

Drexel University and NewLink Genetics

Term Sheet for License Agreement

September 15, 2004

The parties have agreed to the following financial terms for a proposed exclusive license from Drexel University to NewLink Genetics for the use and exploitation of the listed patents. However, the parties recognize that there are other terms that remain to be negotiated. Moreover, the parties are not obligated to enter in to any agreement with one another and no transaction shall be effective unless and until definitive binding legal agreements, incorporating terms and conditions customary to Drexel University license transactions and acceptable to all parties, are executed.

Drexel Patents:

United States	5,879,675	(issued 3/9/99)
	6,361,775	(issued 3/26/02)
Canada	**[*]**	
European	**[*]**	
France	**[*]**	
Great Britain	**[*]**	
Italy	**[*]**	
Germany	**[*]**	

Summary of Key Terms

Exclusive	Exclusive and worldwide license
Fields of Use	All fields of use
Up-front payment	**[*]**
Reimbursement	**[*]** in patent costs and ongoing patent fees and expenses.

Annual payment	
Year 2 (2005)	**[*]**
Year 3 and yearly thereafter	**[*]**
Milestone payments	**[*]**
Royalties	**[*]**
Stacking royalty (if combined with other technologies)	**[*]**
Sublicensing	**[*]**

Accepted and agreed to:

DREXEL UNIVERSITY		NEWLINK GENETICS	
By:	/s/Anil Rastogi	By:	/s/Nicholas Vahanian
	Anil Rastogi, Ph.D. Vice Provost & Vice President Entrepreneurship & Technology Commercialization		Nicholas Vahanian, M.D. Chief Medical and Operations Officer
Date:	Sept. 20, 2004	Date:	Sept. 21, 2004

LICENSE AGREEMENT BETWEEN CENTRAL IOWA HEALTH SYSTEM

AND NEWLINK GENETICS CORPORATION

THIS LICENSE AGREEMENT (the "Agreement"), by and between **CENTRAL IOWA HEALTH SYSTEM**, a not-for-profit corporation, organized and existing under the laws of the state of Iowa ("CIHS"), and **NEWLINK GENETICS CORPORATION**, a Delaware corporation, having a principal place of business at 2901 S. Loop Drive, Ames, Iowa, 50010 ("NEWLINK") is effective as of the 2nd day of August, 2001(the "Effective Date"). CIHS and NEWLINK are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, CIHS owns one hundred percent (100%) interest in the Human Gene Therapy Research Institute located in Des Moines, Iowa ("HGTRI");

WHEREAS, CIHS owns the Inventions, Licensed Patents and Licensed Technology (as hereinafter defined); and

WHEREAS, CIHS has the right to grant, and NEWLINK desires to acquire, licenses to make use and sell certain products utilizing the Licensed Patents and Licensed Technology, and to grant sublicenses upon the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, the Parties agree as follows:

1. DEFINITIONS

1.0 "Active Component" shall mean an ingredient in a Combination Product, which is biologically active and can be used for either therapeutic or preventative purposes, but does not include diluents, vehicles, adjuvants, or any other ingredients which does not have any, or which has only incidental, therapeutic or preventative properties when present alone.

1.1 "Affiliate" shall mean an entity which controls, is controlled by, or is under common control with, a party. For this purpose, "control" means the possession of the power to direct or cause the direction of the management and the policies of an entity, whether through ownership directly or indirectly of fifty percent (50%) or more of the stock entitled to vote, or where control of fifty percent (50%) or more of such rights is not permitted in the country where such entity exists, the maximum permitted in such country.

1.2 "Commercially Reasonable Efforts" shall mean the application of efforts and resources consistent with industry standards for a product of similar market and profit potential. Commercially Reasonable Efforts requires that a Party promptly assign responsibility for such matter to specific employee(s) who are held accountable for the progress of such project.

1.3 "Control" shall mean the ability to grant a license, sublicense, or access as

provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.4 "Invention" shall mean any invention covered by one or more Valid Claims within the Licensed Patents.

1.5 "Field of Use" shall mean the diagnosis, prevention, treatment and mitigation of diseases and conditions in humans, animals, and plants.

1.6 "Licensed Patents" shall mean (a) the patents and patent applications listed in Exhibit A, and (b) all provisionals, divisionals, substitutions, and continuations of the patents and patent applications in Section 1.6(a), as well as any claim in a continuation-in-part patent or application that would be entitled to claim priority to the filing date of one or more of the patents or patent applications in Section 1.6(a), and (c) the patent applications from which the patents listed on Exhibit A issued, excluding those claims within such patent applications that do not cover the inventions claimed in the patents and patent applications listed in Exhibit A, and (d) all reissues, re-examinations, and extensions of any of the preceding patents or of patents issuing on the preceding patent applications, and all foreign counterparts thereof.

1.7 "Licensed Product(s)" shall mean any product useful in the Field of Use, (a) the manufacture, use or sale of which is covered in whole or in part by one or more Valid Claims within the Licensed Patents or (b) that incorporates any Licensed Technology.

1.8 "Licensed Technology" shall mean all proprietary information, know-how, biological, chemical or physical materials, procedures, methods, prototypes, designs, technical data, reports, and pre-clinical data owned or Controlled by HGTRI before and as of the Effective Date that are necessary for NEWLINK to exercise and practice all Valid Claims of the Licensed Patents pursuant to this Agreement, as designated by mutual agreement of the Parties and listed or attached in written format in Exhibit B, after the earlier of (a) NEWLINK's completion of its review of the records and documents at HGTRI relating to such Licensed Technology or (b) six (6) months after the Effective Date. It is understood that NEWLINK's review of such records and documents at HGTRI shall be during such times and subject to such restrictions (including, but not limited to, confidentiality obligations) as the Parties mutually agree. "Licensed Technology" does not include Licensed Patents.

1.9 "Net Sales" shall mean the total amount (in United States dollars) invoiced for sales of the Licensed Product, by NEWLINK, its Affiliates, or Sublicensees to unrelated Third Parties in bona fide arm's length transactions, less the following deductions, in each case related specifically to the Licensed Product in question and actually allowed and taken and not otherwise recovered by or reimbursed to NEWLINK, its Affiliates, or Sublicensees: (a) trade, cash and quantity discounts; (b) taxes on sales (such as sales or use taxes) to the extent added to the sales price and set forth separately as such in the total amount invoiced; (c) freight, insurance and other transportation charges to the extent added to the sales price and set forth separately as such in the total amount invoiced; and (d) amounts repaid or credited by reason of rejections, defects or returns or because of the retroactive price reductions, chargebacks, or rebates under any government programs.

1.10 **"Phase I"**, **"Phase II"** and **"Phase III"** shall mean Phase I, Phase II and

Phase III clinical trials, respectively, in each case as prescribed by the U.S. Food and Drug Administration or a corresponding foreign entity.

1.11 **"Regulatory Approval"** shall mean (a) in the United States, approval by the FDA of an NDA or equivalent application (such as a BLA or PMA) and satisfaction of any related applicable FDA registration and notification requirements (if any); and (b) in any country other than the United States, approval by regulatory authorities having jurisdiction over such country of a single application or set of applications comparable to an NDA and satisfaction of any related applicable regulatory and notification requirements, if any, together with any other approval necessary to make and sell Products commercially in such country.

1.12 **"Sublicensee"** shall mean any Third Party (a) to whom NEWLINK or its Affiliates has granted a license or sublicense under the Licensed Patents to develop, make, have made, import, use, sell, offer for sale, or otherwise exploit a Licensed Product in the Field of Use within the Territory; or (b) to whom NEWLINK or its Affiliates has granted a right to distribute a Licensed Product in the Field of Use in the Territory pursuant to an agreement between NEWLINK and such Third Party; provided that such Third Party has the responsibility for marketing and/or promoting the Licensed Products within the territory in which such distribution rights are granted. For the avoidance of doubt, wholesalers and retailers who do not take such marketing and/or promotion responsibility shall not be Sublicensees.

1.13 **"Term"** shall have the meaning set forth in Section 8.0.

1.14 **"Territory"** shall mean worldwide.

1.15 **"Third Party(ies)"** shall mean any entity other than CIHS, HGTRI or NEWLINK.

1.16 **"Valid Claim"** shall mean either (a) a claim of an issued and unexpired patent included within the Licensed Patents which has not been held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal; or (b) a claim of a pending patent application included within the Licensed Patents, which claim has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application. Notwithstanding the foregoing, if a claim of a pending patent application has not issued as a claim of an issued patent within seven (7) years from the date from which such claim takes priority, such pending claim shall not be a Valid Claim for purposes of the Agreement, unless and until the patent is issued including such claim.

2. GRANT

2.0 **License Grant**. Subject to the reservation of rights set forth in Section 2.1 below, CIHS hereby grants to NEWLINK, upon the terms and conditions herein specified, an exclusive royalty-bearing license, including the right to grant sublicenses, under the Licensed Patents and Licensed Technology to develop, make, have made, use, sell, offer for sale, and import Licensed Products in the Territory and in the Field of Use only.

2.1 Reservation of Rights. The grant in Section 2.0 shall be subject to and non-exclusive with respect to:

(a) The right of CIHS to practice the inventions claimed in the Licensed Patents and to use the Licensed Technology for its own non-commercial bona fide research.

(b) The right of CIHS to license nonexclusively other academic or research institutions to practice the inventions claimed in the Licensed Patents and to use the Licensed Technology for non-commercial research purposes.

(c) The right of CIHS to publish any information included in the Licensed Technology and Licensed Patents provided that NEWLINK shall have the right to review such information prior to publication. CIHS shall provide NEWLINK with a copy of the proposed publication at least thirty (30) days prior to submission of such proposed publication to the publisher. NEWLINK will provide comments, if any, within thirty (30) days of receipt of such proposed publication. If NEWLINK determines that such proposed publication contains Confidential Information of NEWLINK, then NEWLINK may notify CIHS in writing, prior to the expiration of the thirty (30) day period, specifying the information that NEWLINK considers its Confidential Information, and may request that such Confidential Information be deleted from the proposed publication. If NEWLINK determines that the proposed publication contains subject matter for which intellectual property protection should be sought, then NEWLINK may so notify CIHS in writing prior to the expiration of the thirty (30) day period and CIHS shall then delay publication of such information for up to a maximum of sixty (60) days from receipt of such notice solely to enable NEWLINK to file Patent Applications or seek other forms of intellectual property protection as deemed necessary by NEWLINK.

2.2 **Government Rights**. This Agreement is subject to all terms and conditions of Title 35 United States Code Sections 200 through 204, including, without limitation, an obligation that Licensed Products sold or produced in the United States be "manufactured substantially in the United States," and NEWLINK agrees to take all reasonable action necessary on its part as licensee to enable CIHS to satisfy its obligation thereunder, relating to the Licensed Technology and the inventions claimed in the Licensed Patents.

2.3 **Due Diligence**.

(a) NEWLINK agrees to **[*]**, (2) obtain, at a minimum, the**[*]** for NEWLINK (or its Affiliates, and its Sublicensees) to **[*] in [*]** in which **[*]** are projected to provide **[*]** NEWLINK, its Affiliates and Sublicensees, and (3) following receipt of the **[*]** in **[*]** during the Term of this Agreement. As used herein, "**[*]**" shall include but is not limited to, **[*]**.

(i) As part of its Commercially Reasonable Efforts, NEWLINK shall deliver to CIHS, within ninety (90) days of the Effective Date, a **[*]** the **[*]** to **[*]** the **[*]** and **[*]** of **[*]** and **[*]** and **[*]** for the **[*]** of **[*]** of the **[*]**. Every half year thereafter, on or before January 1 and

June 1 of each calendar year, NEWLINK shall provide CIHS with an **[*]** showing the **[*]** commencing upon such half yearly date.

(ii) Within thirty (30) days after January 1 of each year, NEWLINK shall make a written annual progress report ("Progress Report") to CIHS covering the preceding calendar year ending December 31 and detailing the progress of NEWLINK toward commercial use of the Licensed Products. Such report shall include, at a minimum, information sufficient to enable CIHS to satisfy reporting requirements of the U.S. Government and for CIHS to ascertain

progress by NEWLINK toward meeting the diligence requirements of this Section 2.3.

(iii) The sole purpose of the **[*]** and Progress Reports shall be for informational purposes and to enable the Parties to discuss in good faith NEWLINK's compliance with its obligation to use Commercially Reasonable Efforts as set forth in this Section 2.3. The reporting obligations of NEWLINK under Sections 2.3(a)(i) and 2.3(a)(ii) shall expire upon the commencement of NEWLINK's reporting obligations under Section 2.3(b).

(b) Commencing ninety (90) days after commercial launch of a Licensed Product in a country and within sixty (60) days after December 31 of each calendar year thereafter, NEWLINK shall provide written annual reports to CIHS which shall include but not be limited to: reports of progress on research and development, Regulatory Approvals received for Licensed Products, manufacturing, sublicensing, marketing and sales activities by NEWLINK, its Affiliates or Sublicensees during the preceding twelve (12) months, as well as, plans of such activities for the coming year. NEWLINK shall also deliver to CIHS a copy of its annual report to stockholders, promptly following the availability of such report.

(c) Without limiting the foregoing, NEWLINK shall have the specific obligation to achieve the following diligence milestones:

(i) Within **[*]** after the Effective Date, either (a) NEWLINK will have expended **[*]** for research and development related to the Inventions; or (b) NEWLINK will have raised **[*]** in equity capital;

(ii) Within **[*]** after the Effective Date, either (a) NEWLINK or its Sublicensee will have developed a Licensed Product through **[*]** or (b) NEWLINK will have expended **[*]** for research and development related to the Inventions; or (c) NEWLINK will have raised an aggregate of **[*]** in equity capital, including the equity capital amount set forth in subsection (i) above;

(iii) Within **[*]** years after the Effective Date, either (a) NEWLINK or its Sublicensee will have commenced **[*]** on a Licensed Product; or (b) NEWLINK will have expended **[*]** for research and development related to the Invention; or (c) NEWLINK will have raised an aggregate of **[*]** in equity capital, including the equity capital amounts of subsections (i) and (ii) above;

(d) In addition, NEWLINK shall use Commercially Reasonable Efforts to negotiate appropriate sponsored research programs with researchers at CIHS in connection with the development of Licensed Products or other product opportunities in the Field of Use, as funds become available to NEWLINK for basic research. Funds provided by NEWLINK for such sponsored research programs may be used to satisfy the diligence milestones set forth in Section 2.3(c).

(e) NEWLINK shall use Commercially Reasonable Efforts to grant sublicenses for the development and commercialization of Licensed Products within the Field of Use that are not otherwise being diligently developed or commercialized by NEWLINK, its Affiliates or Sublicensees; provided however, that in no event shall NEWLINK be obligated to grant to any Third Party a sublicense if such Third Party is a **[*]** or **[*]**, or if the grant of such sublicense would reasonably have an adverse effect on NEWLINK's, its Affiliate's or

Sublicensee's development or commercialization of Licensed Products in the field of **[*]**. CIHS recognizes that NEWLINK will initially focus its development efforts on a few products of strategic importance, and agrees that NEWLINK's Commercially Reasonable Efforts hereunder will be evaluated in view of NEWLINK's available resources and financing stage.

2.4 Failure to Meet Due Diligence Requirements.

(a) In the event that NEWLINK fails to meet the diligence milestones of Section 2.3(c)(i), the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially satisfied its diligence obligations under this Agreement. If CIHS, in good faith, reasonably concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have six (6) months to cure such failure. In the event that NEWLINK fails to meet the diligence milestones of Sections 2.3(c)(ii) or 2.3(c)(iii), the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially satisfied such diligence obligation under this Agreement. If CIHS, in good faith, concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have three (3) months to cure such failure. In each case, if NEWLINK fails to cure its failure to meet the appropriate milestone within the applicable cure period, CIHS shall have the right, at its option, to either terminate, or convert to non-exclusive, the license granted under Section 2.0 of this Agreement.

(b) In addition to Section 2.4(a), if CIHS determines in its reasonable good faith judgement that NEWLINK has failed to (i) use Commercially Reasonable Efforts to develop or commercialize the Licensed Products in a particular field within the Field of Use, and/or (ii) use

Commercially Reasonable Efforts to grant sublicenses for the development and commercialization of Licensed Products within the Field of Use that are not otherwise being diligently developed or commercialized by NEWLINK, its Affiliates or Sublicensees, pursuant to Section 2.3(e), then CIHS shall so notify NEWLINK in writing, and following such notice, the Parties shall in good faith review for a period of thirty (30) days whether NEWLINK has materially

satisfied such diligence obligations. If CIHS, in good faith, reasonably concludes that NEWLINK has failed in this respect, it shall so notify NEWLINK in writing and NEWLINK shall then have six (6) months to cure such failure. If NEWLINK fails to cure such failure within the applicable cure period, CIHS shall have the right, at its option, to either terminate, or convert to non-exclusive, the license granted under Section 2.0 of this Agreement with respect to such particular field.

2.5 Sublicenses.

(a) General. The license granted to NEWLINK under Section 2.0 of this Agreement shall include the right to grant sublicenses. Any sublicenses granted by NEWLINK under this Agreement shall be subordinate to the terms and conditions of this Agreement. NEWLINK shall promptly notify CIHS of the identity and address of each Sublicensee with whom it concludes a sublicense agreement and agrees to provide to CIHS a redacted copy of each such sublicense agreement sufficient in scope to ensure compliance with the terms of this Agreement.

(b) Assignment of Sublicenses. Upon request by a Sublicensee, and at CIHS's discretion, a sublicense granted by NEWLINK under the Licensed Patents and Licensed Technology shall remain in effect and be assigned to CIHS in the event this Agreement terminates, but only to the extent such sublicense is consistent with the terms of this Agreement and is not in breach thereof.

3. ROYALTIES AND MILESTONES

3.0 License Issue Fee. In partial consideration of the licenses granted under Section 2.0, NEWLINK shall enter into a stock purchase agreement with the Stoddard Cancer Research Institute (a d.b.a. of CIHS) in the form attached hereto as Exhibit C (the "Stock Purchase Agreement") concurrently with the execution of this Agreement, which Stock Purchase Agreement shall be consistent with the terms set forth in subsections (a) and (b), as follows:

(a) NEWLINK shall issue, **[*]** to the Stoddard Cancer Research Institute, **[*]** shares of NEWLINK's common stock (the "Shares"); and

(b) In addition, the Stock Purchase Agreement shall provide that CIHS shall have the following rights with respect to such Shares:

(i) The right to transfer the Shares;

(ii) Voting rights;

(iii) The right to purchase additional shares of stock of NEWLINK on the same terms and conditions as those offered to NEWLINK's potential investors in such financing round, to maintain CIHS' or its designee's pro-rata ownership in NEWLINK; and

(iv) Piggy back registration rights beginning no later than six months

following an initial public offering of NEWLINK stock.

3.1 Patent Fees and Expenses. Additionally, NEWLINK shall reimburse CIHS for any out-of-pocket patent fees and expenses incurred by CIHS for filing, prosecuting and maintaining the Licensed Patents **[*]**, subject to the following: (a) if NEWLINK fails or elects not to pay any such patent fees or expenses with respect to a patent or patent application within thirty (30) days after an invoice therefor from CIHS, NEWLINK's rights and licenses granted to NEWLINK hereunder with respect to such patent or patent application shall immediately terminate and such patent application or patent shall no longer be included in Licensed Patents; and (b) if NEWLINK disputes its obligation to pay any out-of-pocket patent fees and expenses invoiced by CIHS pursuant to Section 3.1, then the Parties shall for thirty (30) days in good faith attempt to resolve the dispute, provided that NEWLINK shall not thereby be relieved of its obligations to make timely payment of any and all undisputed amounts when due to CIHS.

3.2 Royalties. Subject to the terms and conditions of this Agreement, commencing on the Effective Date of this Agreement, NEWLINK shall pay CIHS royalties on Net Sales of Licensed Products by NEWLINK, its Affiliates and Sublicensees on a country-by-country and Licensed Product-by-Licensed Product basis as follows:

(a) In countries where the manufacture, use, sale, offer for sale, or import of Licensed Products would, but for the grant of the license under the Agreement, infringe a Valid Claim of the Licensed Patents, NEWLINK shall pay to CIHS a royalty on Net Sales of Licensed Products in such countries at a rate equal to **[*]** of annual Net Sales of Licensed Products. In the event that the manufacture, sale or use of any Licensed Product is not covered by a Valid Claim within the Licensed Patents in a country, then NEWLINK shall pay to CIHS a royalty with respect to Net Sales in such country of such Licensed Products by NEWLINK, its Affiliates and Sublicensees at a rate equal to **[*]**.

(b) The royalty obligations of NEWLINK shall expire on a country-by-country and Licensed Product-by-Licensed Product basis upon the later of (i) the expiration of the last to expire Valid Claim within the Licensed Patents covering the Licensed Product in a country (such expiration to occur only after expiration of extensions of any nature to such patents which may be obtained under applicable statutes or regulations in the respective countries of the Territory, such as the Drug Price Competition and Patent Term Restoration Act of 1984 in the U.S.A., and similar patent extension laws in other countries), or (ii) until twelve (12) years following the first commercial sale of a Licensed Product in a country. Following expiration of the royalty obligations for each Licensed Product in each country, NEWLINK shall retain a fully-paid, **[*]** license under the Licensed Technology to make, have made, use, sell, offer for sale, and import such Licensed Products in such country.

(c) Combination Products. Sales of any products that contain one or more Licensed Products and one or more Active Component(s) that is not a Licensed Product ("Combination Product") shall be determined as follows. Net Sales shall first be calculated in accordance with the definition of Net Sales set forth in Section 1.10, and then multiplied by the fraction, A/A + B, where A is the invoiced sales price charged for the Licensed Products included in such Combination Product and B is the invoiced sales price charged for the other Active Component(s) included in the Combination Product. If there are no separate sales of such Active Component(s), Net Sales of the Combination Product shall first be determined in accordance with

the definition of Net Sales set forth in Section 1.10, and then multiplied by a fraction, A/C, where A shall be the invoiced sales price of the Licensed Products included in such Combination Product and C shall be the invoiced sales price of the Combination Products. If neither the Licensed Product nor the other Active Component(s) included in such Combination Product are sold separately, then Net Sales of the Combination Product shall be first determined in accordance with the definition of Net Sales set forth in Section 1.10, as adjusted by a mechanism to be agreed upon by the Parties in good faith based upon the respective fair market values of such Licensed Product and such Active Component(s). The cost in each case shall be determined in accordance with generally accepted accounting principles of the United States.

(d) Notwithstanding the foregoing, in no event shall the royalties owed to CIHS on a given Licensed Product under Section 3.2(a) be less than **[*]** of Net Sales (as defined in Section 1.10) in the case of Licensed Products covered by a Valid Claim, or less than **[*]** of Net Sales (as defined in Section 1.10) in the case of Licensed Products not covered by a Valid Claim.

3.3 Minimum Royalties. Following the First Commercial Launch of Licensed Product, NEWLINK shall pay to CIHS a minimum annual royalty as follows: Prior to December 31 of the calendar year in which the first Licensed Product is Commercially Launched, NEWLINK shall pay to CIHS **[*]** ("Initial Payment"). A second payment of **[*]** shall be due on the first anniversary of the Initial Payment. Prior to each of the second and third anniversaries of the Initial Payment, NEWLINK shall pay CIHS **[*]**, and prior to the fourth and fifth anniversaries of the Initial Payment, NEWLINK shall pay CIHS **[*]**. Any royalties resulting from Net Sales of Licensed Products in a given year may be credited against the minimum royalty due for that year. For purposes of this Section 3.3, "First Commercial Launch" or "Commercially Launched" shall mean, with respect to each Licensed Product in each country, the first bona fide commercial sale of a Licensed Product in a country by or under authority of NewLink, its Affiliates or Sublicensees, including without limitation, any offer for sale or sale made by NewLink, its Affiliates or Sublicensees to a Third Party pursuant to a written agreement.

3.4 Sublicensing Fee. In addition to the amounts owed by NewLink to CIHS pursuant to Section 3.0, 3.1, 3.2, and 3.3 above, if NEWLINK grants a sublicense of its rights hereunder to a Third Party, NEWLINK agrees to pay to CIHS a sublicensing fee of **[*]** of any **[*]** and other consideration (other than **[*]** or **[*]** on **[*], and [*]** within **[*]** of **[*]**) (collectively, the "Sublicensing Fee") received by NEWLINK from each Sublicensee in consideration for the grant of a sublicense of the Licensed Patents or development of a Licensed Product.

3.5 Third Party Royalties. NEWLINK shall be responsible for all Third Party payments and/or licenses of Third Party technology necessary to practice the Licensed Patents and Licensed Technology to make, use or sell Licensed Products ("Necessary Rights"). In the event that NEWLINK pays royalties to Third Parties pursuant to a written agreement under which it obtains Necessary Rights for a particular Licensed Product in a particular country(ies) (each a "Third Party Agreement"), NEWLINK may offset, on a Licensed Product-by-Licensed Product and country-by-country basis, up to **[*]** of the royalties due under such Third Party Agreements against royalties which are due CIHS hereunder for such Licensed Product in such country(ies), in each case, in such calendar year. Notwithstanding the foregoing, the royalty due to CIHS as set forth in Section 3.2 in each calendar quarter for any Licensed Product shall not be reduced to less than **[*]** of that (or, i.e., **[*]** of Net Sales for Licensed Products covered by a Valid Claim in such country, and **[*]** of Net Sales for Licensed Products not covered by a Valid Claim in such country).

3.6 Schedule and Form of Payment/Taxes.

(a) Following the first commercial sale of a Licensed Product, NEWLINK shall make quarterly written reports to CIHS within thirty (30) days after the end of each calendar quarter, stating in each such report the aggregate Net Sales of Products sold by NEWLINK, its Affiliates and Sublicensees during the calendar quarter. Simultaneously with the delivery of each such report, NEWLINK shall pay to CIHS the total royalties, if any, due to CIHS for the period of such report. If no royalties are due, NEWLINK shall so report. Neither Party shall provide to Third Parties any information contained in reports provided to such Party pursuant to this Section 3.6, except as required by a Party's agreements with its licensors.

(b) All amounts payable to CIHS hereunder shall be payable in United States dollars. All amounts payable to CIHS hereunder shall be payable in United States dollars in Iowa, or at such other place as CIHS may reasonably designate, provided, however, that if the law of any foreign country prevents any payment payable to CIHS hereunder to be made in Iowa, or otherwise designated by CIHS or prevents any such payment to be made in United States dollars, CIHS agrees to accept such royalty in form and place as permitted, including deposits by NEWLINK in the applicable foreign currency in a local bank or banks in such country designated by NEWLINK. If any currency conversion is required in connection with any payments to CIHS hereunder, such conversion shall be made at the buying rate for the transfer of such other currency as quoted by CITICORP BANK (NEW YORK) on the last business day of the applicable accounting period, in the case of any payment payable with respect to a specified accounting period, or in the case of any other payment, the last business day prior to the date of such payment. All such payments shall be paid in United States dollars, originated from a United States bank located in the United States and made by bank wire transfer in immediately available funds to such account as the receiving party shall designate.

(c) Where required to do so by applicable law or treaty, NEWLINK shall withhold taxes required to be paid to a taxing authority on account of such income to CIHS, and NEWLINK shall furnish CIHS with satisfactory evidence of such withholding and payment in order to permit CIHS to obtain a tax credit or other relief as may be available under the applicable law or treaty.

(d) Any amounts payable to CIHS hereunder that are not paid on the date such payments are due under this Agreement shall accrue interest from the due date until paid, at a rate equal to **[*]** per month (or the maximum allowed by law, if less). Said

interest and the payment and acceptance thereof shall not negate or waive the right of CIHS to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment.

3.7 Records. NEWLINK shall maintain complete and accurate records showing gross sales, deductions and other relevant information sufficient to enable accurate calculation of royalties on a country-by-country and Licensed Product-by-Licensed Product basis and other fees payable hereunder by NEWLINK to CIHS. NEWLINK shall, at CIHS's request and expense, provide certified statements from NEWLINK's auditors, concerning royalties and other fees due pursuant to this Agreement. Once a calendar year, CIHS shall have the right to select a certified public accountant to inspect, on

reasonable notice and during regular business hours, the records of NEWLINK to verify NEWLINK's statements and royalty payments due pursuant to this Agreement. Inspections conducted under this Section 3.7 shall be at CIHS's expense, provided, if such an audit correctly uncovers a deficiency in payment of royalties payable by NEWLINK hereunder, NEWLINK shall immediately pay to CIHS such deficient amount, and if the amount of any such deficiency is greater than five percent (5%) of the total amount due during the audited period, NEWLINK shall bear the reasonable out of pocket expenses of such accounting firm to conduct such audit. Records shall be preserved by NEWLINK for five (5) years for inspection by CIHS.

4. PROSECUTION AND MAINTENANCE OF LICENSED PATENTS

4.0 Prosecution. CIHS shall, using patent counsel of its choice, have the initial right to control the preparing, filing, prosecuting and maintaining patent applications and patents within the Licensed Patents. CIHS shall provide NEWLINK a reasonable opportunity to review and comment upon all such filings prior to their submission to patent authorities. If CIHS elects not to pursue any patent application or patent within the Licensed Patents, CIHS shall notify NEWLINK reasonably in advance of any filing deadline or material date and NEWLINK shall have the right, but not the obligation, to assume control of the preparation, filing, protection and maintenance of such patent or patent application, at its expense.

4.1 Payment of Costs. NEWLINK shall pay all costs incurred in connection with preparing, filing, prosecuting and maintaining patent applications and patents within the Licensed Patents that accrue on or after January 1, 2000. In the event that NEWLINK decides not to continue to pay costs related to a particular patent/patent application within the Licensed Patents in a particular country, NEWLINK shall timely notify CIHS in writing thereof, and concurrent with such notice, NEWLINK's rights under this Agreement to practice the inventions under such patent/patent application within the Licensed Patents in such country shall immediately terminate.

4.2 Patent Enforcement.

(a) Each Party shall notify the other Party in writing of any alleged or threatened infringement of Licensed Patents of which it becomes aware and which may adversely impact the rights of the Parties hereunder.

(b) NEWLINK shall have the first right, but not the obligation, to prosecute any infringement of the Licensed Patents or defend any declaratory judgment with respect to the

Licensed Patents. If NEWLINK elects to commence an action described above, CIHS may, to the extent permitted by law, elect to join as a party to the action. Any recovery obtained in such an action shall be used first to reimburse costs of NEWLINK, then CIHS, in prosecuting such action (including reasonable attorney's fees). Any remainder of the recovery shall be distributed as follows: **[*]**. CIHS shall have the right, but not the obligation, to prosecute any such infringement of the Licensed Patents if NEWLINK does not elect to do so within one hundred eighty (180) days after the Parties become aware of allegedly infringing activities. Any recovery obtained in such an action brought by CIHS under the preceding sentence shall be used first to reimburse costs of CIHS, then NEWLINK, in prosecuting such action (including reasonable attorney's fees). Any remainder of the recovery shall be distributed as follows: **[*]**.

4.3 Control of Third Party Enforcement Actions. During the term of this Agreement, either Party that brings an action to enforce the Licensed Patent shall prosecute such action, at its own expense, utilizing counsel of its choice, subject to reimbursement of costs pursuant to Section 4.2(b). No settlement, consent judgment or other voluntary final disposition of any such suit may be entered into without the written consent of the other Party, which consent shall not unreasonably be withheld.

4.4 Cooperation. In any suit to enforce and/or defend the Licensed Patent pursuant to this Agreement, the Party not in control of such suit shall, at the request and expense of the controlling Party, cooperate in all respects and, to the extent reasonably possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like. Any out-of-pocket costs incurred by the Party not in control of such suit shall be promptly reimbursed by the Party controlling such suit, subject to reimbursement pursuant to Section 4.2(b).

4.5 Activities for Licensed Products Infringing Rights of Third Parties. Each Party shall promptly notify the other if any legal proceedings are commenced or threatened against either Party alleging that the manufacture, use, sale or possession of the Licensed Product infringes a Third Party's patent or other intellectual property rights. In such event, the Parties shall meet to discuss the course of action to be taken with respect to an enforcement action with respect to such infringement or misappropriation.

5. MARKINGS

5.1 Product Markings. NEWLINK shall mark all Licensed Products (or their containers or labels) made, sold, or otherwise disposed of by NEWLINK, its Affiliates or Sublicensees, under the license granted in this Agreement, in accordance with all applicable United States and foreign statutes pertaining to the marking of products with patent pending, patent number(s), copyrights, or other intellectual property notices and legends required to maintain the intellectual property rights licensed in this Agreement.

6. CONFIDENTIALITY

6.0 Confidential Information. Except as expressly provided herein, the Parties agree that, for the term of this Agreement and for five (5) years thereafter, the receiving Party shall not publish or otherwise disclose and shall not use for any purpose any Confidential Information furnished to it by the other Party hereto pursuant to this Agreement. For purposes of this Agreement, "Confidential Information" shall mean all nonpublic technical and/or business information (whether patentable or copyrightable), including without limitation, inventions, unpublished and draft patent applications and any information contained therein, formulae, trade secrets, processes, laboratory notebooks, reports, technical data and technology, that is owned or possessed by the disclosing Party and furnished or otherwise made available to the receiving Party either (a) between January 1, 1999 and the Effective Date ("Pre-Agreement Period") or (b) after the Effective Date, provided that such information is either (i) disclosed in writing and marked "Confidential," or in a similar manner, to indicate its confidential nature, or (ii) if disclosed orally, is confirmed in writing as confidential within forty-five (45) days following such

disclosure. Notwithstanding the foregoing, the Parties understand and agree that the marking and reduction to writing requirements of subsections (i) and (ii) above shall not apply to Confidential Information disclosed during the Pre-Agreement Period.

6.1 Confidential Information Exclusions. Notwithstanding the provisions of Section 6.0, the obligation of confidentiality shall not apply to information that the receiving Party can demonstrate:

(a) is now in the public domain or which becomes generally available to the public through no fault of the receiving Party; or

(b) is already known to, or in the possession of, the receiving Party prior to disclosure by the disclosing party as can be demonstrated by documentary evidence; or

(c) is disclosed on a non-confidential basis from a Third Party having the right to make such a disclosure; or

(d) is independently developed by the receiving Party (without the use of any Confidential Information) as can be demonstrated by competent documentary evidence.

6.2 Permitted Usage. Notwithstanding the provisions of Section 6.0 above, the receiving Party may use or disclose Confidential Information of the disclosing Party to the extent necessary to exercise the rights granted to it hereunder (provided it uses reasonable efforts to protect such information commensurate with the efforts used to protect its own information) in prosecuting or defending litigation, complying with applicable governmental regulations and/or submitting information to tax or other governmental authorities; provided that if the receiving Party is required by law to make any public disclosures of Confidential Information of the disclosing Party, to the extent it may legally do so, it will give reasonable advance notice to the disclosing Party of such disclosure and will use its reasonable efforts to secure confidential treatment of Confidential Information prior to its disclosure (whether through protective orders or otherwise).

7. WARRANTIES AND INDEMNITIES

7.0 Representations and Warranties.

(a) NEWLINK hereby represents and warrants that (i) it has the authority and right to enter into and perform this Agreement, and has taken all necessary corporate or other action and obtained all necessary approvals to do so, and (ii) its execution, delivery and performance of this Agreement does not and will not conflict with any other agreement to which it is or becomes a party or by which it is or becomes bound.

(b) CIHS hereby represents and warrants that to the best of its knowledge as of the Effective Date, all rights, interest, and title in and to the Invention has been properly assigned by all inventors thereof to HGTRI.

7.1 CIHS MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT USE OF A LICENSED PRODUCT OR A PRODUCT MADE USING A LICENSED PROCESS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS OF THIRD PARTIES.

7.2 Indemnities.

(a) NEWLINK agrees to indemnify, hold harmless and defend CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents from and against all losses, liabilities, damages, costs and expenses (including without limitation, reasonable attorney's fees and other expenses of litigation) ("Liabilities") arising from any claims, demands, actions or other proceedings ("Claims") by any and all Third Parties for **[*]** arising out of (i) **[*]**, under this Agreement and (ii) **[*]**; provided however, that NEWLINK shall not be obligated to indemnify, hold harmless and defend CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents from and against any Liabilities arising from any Claims arising out of the **[*]** of CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents.

(b) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, WHATSOEVER, WHETHER GROUNDED IN TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, CONTRACT OR OTHERWISE. CIHS SHALL NOT HAVE **[*]** WITH RESPECT TO LICENSED PRODUCT(S).

(c) NEWLINK shall at all times comply, through insurance or self-insurance, with all statutory workers' compensation and employers' liability requirements covering any and all employees with respect to activities performed under this Agreement.

7.3 Insurance. In addition to the foregoing, NEWLINK shall maintain during the term of this Agreement, Comprehensive General Liability Insurance, including Products Liability Insurance, with reputable and financially secure insurance carrier(s) to cover the indemnity granted in Section 7.2. NEWLINK shall maintain an insurance policy that provides minimum limits of liability as follows: beginning on the Effective Date to the commencement of the first clinical trial of any Licensed Product, the minimum limit shall be two million dollars ($2,000,000); beginning on the commencement of the first clinical trial of any Licensed Product to the commencement of the first Phase III clinical trial of any Licensed Product, the minimum limit shall increase to ten million dollars ($10,000,000); and beginning on the first Phase III clinical trial of any Licensed Product to the termination or expiration of this Agreement, the minimum limit shall increase to twenty million dollars ($20,000,000). Such insurance shall include CIHS, HGTRI, and their respective trustees, officers, employees, students, and agents as additional insureds. Such insurance shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement and should be placed with carriers with ratings of at least A- as rated by A.M. Best. Within fifteen (15) days of the Effective Date of this Agreement, NEWLINK shall furnish a Certificate of Insurance evidencing primary coverage and additional insured requirements and requiring thirty (30) days prior notice of cancellation or material change to CIHS. NEWLINK shall advise CIHS, in writing, that it maintains excess liability

coverage (following form) over primary insurance for at least the minimum limit set forth above. All such insurance of NEWLINK shall be primary coverage.

8. TERM AND TERMINATION

8.0 Term. Unless previously terminated as herein provided, the term of this Agreement shall commence upon the Effective Date and expire on the date when NEWLINK has no further royalty obligations hereunder.

8.1 Termination.

(a) This Agreement may be terminated prior to its expiration under Section 8.0 under the following circumstances:

(i) If a Party commits material breach of this Agreement, the non-breaching Party at its option, may terminate this Agreement by giving the breaching Party written notice of its election to terminate as of a stated date, not less than forty-five (45) days from the date of the notice. Such notice shall state the nature of the defaults claimed by the non-breaching Party. The breaching Party may, during such forty-five (45) day period, or such longer period as may be specified in such notice, correct any default stated in such notice and if such default is corrected, this Agreement shall continue in full fame and effect as if such notice had not been given.

(ii) This Agreement may be terminated by NEWLINK, at will, at any time upon not less than sixty (60) days prior written notice to CIHS.

(b) NEWLINK may terminate its license with respect to a specific patent or patent application within the Licensed Patents, at will, at any time upon not less than ninety (90) days prior written notice to CIHS. In such event, the specified patent application or patent shall no

longer be a Licensed Patent and NEWLINK shall retain an exclusive license to the remaining patents and patent applications within the Licensed Patents.

8.2 Effect of Termination.

(a) Accrued Obligations. Termination of this Agreement for any reason shall not release either Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

(b) Termination of Agreement. In the event of any early termination of this Agreement, whether by CIHS pursuant to Section 2.4(a) due to NEWLINK's failure to meet one or more of its diligence obligations, or by CIHS pursuant to Section 8.1(a)(i) due to NEWLINK's material breach, or by NEWLINK pursuant to Section 8.1(a)(ii), in each case:

(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products, and all practice or use of the Licensed Patents and Licensed Technology; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology.

(c) Termination of a patent within the Licensed Patents. In the event of any early termination of NEWLINK's license to a particular patent and/or patent application within the Licensed Patents, whether by NEWLINK pursuant to Section 8.1(b), or by CIHS pursuant to Section 4.1, in each case:

(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products relating to such patent or patent application, and all practice or use of such patent or patent application; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products relating to such patent or patent application that is in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology relating to such patent or patent application, unless such Confidential Information or Licensed Technology also relates to patents or patent applications with respect to which NEWLINK still retains a license under this Agreement.

(d) Termination of a field within the Field. In the event of any termination of NEWLINK's license to a particular field within the Field, by CIHS pursuant to Section 2.4(b):

(i) NEWLINK, its Affiliates and Sublicensees shall immediately cease all development and commercialization of Licensed Products in such field, and all practice or use of Licensed Patents and Licensed Technology in such field; provided, however, that NEWLINK, its Affiliates, Sublicensees and distributors shall have the right to sell or otherwise distribute Licensed Products in such field that is in their inventories or otherwise in their control as of such termination of this Agreement for a period not to exceed three (3) months from such termination.

(ii) NEWLINK shall return, or destroy, at CIHS's option, all Confidential Information of CIHS, including any copies of any Licensed Technology relating to field, unless such Confidential Information or Licensed Technology also relates to Licensed Patents, Licensed Technology or Licensed Products in a field with respect to which NEWLINK retains a license under this Agreement.

8.3 Survival. Articles 1, 5, 6, and 9, and Sections 2.5(b), 3.2-3.7, 4.5, 7.1, 7.2, 8.2 and 8.3 of this Agreement shall survive expiration or termination of this Agreement.

9. MISCELLANEOUS

9.0 Notices. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered, sent by courier, sent by registered or certified mail, return receipt requested, postage prepaid, or sent via facsimile in each case to the respective address specified below, or such other address as may be specified in writing to the other Party hereto:

CIHS:
Central Iowa Health System
1200 Pleasant Street
Des Moines, Iowa 50309
Attn: President
Fax: 515-241-5994

with copies to:
Wilson Sonsini Goodrich & Rosati
Professional Corporation
650 Page Mill Road
Palo Alto, California 94304-1050
Attn: Kenneth A. Clark, Esq.
Fax: (650) 493-6811

Iowa Health System
1200 Pleasant Street
Des Moines, Iowa 50309
Attn: General Counsel
Fax: 515-241-4656

NEWLINK:
NEWLINK Genetics Corporation
2901 S. Loop Drive
Ames, Iowa 50010
Attn: Chairman

Fax: 515-296-5557

with a copy to:
Cooley Godward, L.L.P.
380 Interlocken Crescent
Suite 900
Broomfield, CO 80021-8023
Attn: James C. Linfield, Esq.
Fax: (650) 493-6811

Any such notice mailed by registered or certified mail or air express shall be deemed to have been given when mailed, as evidenced by the date on the receipt retained by the sender. Either Party may change the address to which notices to it are to be given by notice as provided herein.

9.1 Force Majeure. Neither Party to this Agreement shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of God, fires, earthquakes, strikes and labor disputes, acts of war, civil unrest, or intervention of any governmental authority, provided that the affected Party shall use reasonable efforts to remedy any such delay or failure.

9.2 Assignments. Except as provided in this Section 9.2, this Agreement may not be assigned by NEWLINK without the written prior consent of CIHS, which consent shall not be unreasonably withheld, provided that NEWLINK may assign this Agreement without CIHS' prior consent to an Affiliate or in connection with the sale or transfer of all or substantially all the assets of NEWLINK relating to the Agreement. CIHS may assign this Agreement at its discretion.

9.3 Injunctive Relief. The Parties acknowledges that the terms hereunder are necessary and reasonable to protect the Parties, and expressly agree that monetary damages may not be a sufficient remedy for any breach of this Agreement, and therefore the breaching Party will not oppose the non-breaching Party's requests for injunctive relief as a remedy for any such breach. In addition, the Parties agrees that they shall be entitled to seek temporary and permanent injunctive relief against any threatened violation of the terms of this Agreement or the continuation of any such violation in any court of competent jurisdiction, without the necessity of proving actual damages or the posting of any bond. For avoidance of doubt, any such equitable remedies shall be cumulative and not exclusive and are in addition to any other remedies, which either Party may have under this Agreement or applicable law.

9.4 Severability. In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision. In such event, the parties shall in good faith negotiate an amendment providing a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.

9.5 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not act as a waiver of such obligation. No waiver, modification,

release, or amendment of any obligation under this Agreement shall be valid or effective unless in writing and signed by both Parties hereto.

9.6 Successors in Interest. This Agreement shall inure to the benefit of and be binding on the Parties' permitted assigns, successors in interest, and subsidiaries.

9.7 Independent Contractors. The Parties hereto agree that each is acting as an independent contractor and not as an agent of the other or as joint venturers.

9.8 Choice of Law and Jurisdiction. This Agreement is subject to and shall be construed and enforced in accordance with the laws of the U.S.A. and the State of Iowa.

9.9 Entire Agreement. This Agreement together with the Exhibits attached hereto, constitute the entire agreement between the Parties as to the subject matter hereof, and all prior negotiations, representations, agreements and understandings are merged into, extinguished by and completely expressed by this Agreement.

9.10 Headings. The captions to the several Sections and Articles hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.

9.11 Counterparts. This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS WHEREOF, the Parties have duly executed this Agreement effective as of the Effective Date.

NEWLINK GENETICS CORPORATION	**CENTRAL IOWA HEALTH SYSTEM**
By: /s/	By: /s/
Title: Chairman	Title: President

Country	Reference	Type	Filed	Serial #	Issued	Patent#	Status
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EXHIBIT "A"

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EXHIBIT “B”

EXHIBIT “C”

Stock Purchase Agreement with the Stoddard Cancer Research Institute

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NEWLINK GENETICS CORPORATION

STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (the “Agreement”) is made this 2nd day of August, 2001, between Newlink Genetics Corporation, a Delaware corporation (the “Company”), and Stoddard Cancer Research Institute, a d.b.a. of Central Iowa Health System, an Iowa non-profit corporation, (the “Purchaser”).

1. Sale of Stock. The Company hereby agrees to sell to the Purchaser and the Purchaser hereby agrees to purchase an aggregate of **[*]** shares of the Company’s Common Stock (the “Shares”).

2. Payment of Purchase Price. The purchase price for the Shares shall be deemed paid by Purchaser’s grant of licenses to the Company pursuant to Section 2.0 of the License Agreement dated August 2, 2001 between Purchaser and the Company.

3. Representations and Warranties of the Company. The Company represents and warrants to the Purchaser as follows:

(a) Organization and Standing. The Company is a corporation duly organized and validly existing under, and by virtue of, the laws of the State of Delaware and is in good standing under such laws. The Company has requisite corporate power and authority to own and operate its properties and assets, and to carry on its business as presently conducted. The Company is duly qualified to do business as a foreign corporation in each jurisdiction in which the failure to be so qualified will have a material adverse affect on the Company's business.

(b) Corporate Power; Authorization. The Company has all requisite legal and corporate power and authority to execute and deliver this Agreement and to issue the Common Stock sold under this Agreement. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization, execution, delivery and performance of this Agreement and the performance of all of the Company's obligations under this Agreement has been taken. The Shares, when issued in compliance with the provisions of this Agreement will be validly issued, fully paid and nonassessable.

(c) Capitalization. The authorized capital stock of the Company consists or will, upon the execution of the Agreement, consist of 12,000,000 shares of Common Stock and 3,000,000 shares of Preferred Stock, 1,600,000 of which is designated Series A Preferred Stock. Immediately prior to the execution of this Agreement, 5,198,200 shares of Common Stock and 420,000 shares of Series A Preferred Stock will be issued and outstanding. No other shares of capital stock will be outstanding. All of the issued and outstanding shares of Common Stock and Series A Preferred Stock are duly authorized, validly issued, fully paid and nonassessable, and were issued in compliance with applicable federal and state securities laws. Except for (i) the conversion privileges of the Series A Preferred Stock, (ii) 188,000 shares of Common Stock subject to issued options issued under the Company's 2000 Equity Incentive Plan, and (iii) 1,500,000 shares of Common Stock reserved for future issuance pursuant to the Company's Equity Incentive Plan and (iv) the rights provided in the Company's Investors' Rights Agreement, there are no other outstanding shares of capital stock or outstanding rights of first refusal, preemptive rights or other rights, options, warrants, conversion rights, or other

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agreements either directly or indirectly for the purchase or acquisition from the Company of any shares of its capital stock.

4. Representations and Warranties of the Purchaser. Purchaser represents and warrants to the Company as follows:

(a) Restricted Securities. Purchaser is aware that the Shares to be issued to Purchaser by the Company pursuant to this Agreement have not been registered under the Securities Act of 1933, as amended (the "Act"), and that the Shares are deemed to constitute "restricted securities" under Rule 144 promulgated under the Act.

(b) Accredited Investor. Purchaser is an accredited investor within the meaning of Regulation D prescribed by the Securities and Exchange Commission pursuant to the Act.

(c) Investment Experience. By virtue of such Purchaser's experience in evaluating and investing in private placement transactions of securities in companies similar to the Company, Purchaser has sufficient knowledge and experience in business and financial matters to evaluate the Company, its proposed activities and is capable of evaluating the merits and risks of such Purchaser's investment in the Company, Purchaser has the capacity to protect such Purchaser's own interests in connection with the purchaser of the Shares by virtue of the business or financial expertise of any professional advisors to Purchaser who are unaffiliated with and who are not compensated by the Company or any of its affiliates, directly or indirectly. Purchaser has the ability to accept the high risk and lack of liquidity inherent in this type of investment.

(d) Investment Intent. Purchaser is acquiring the Securities for investment for such Purchaser's own account and not with a view to, or for resale in connection with, any distribution thereof. Purchaser understands that the Securities have not been registered under the Act by reason of a specific exemption from the registration provisions of the Act that depends upon, among other things, the bona fide nature of the investment intent as expressed herein.

(e) Rule 144. Purchaser understands that the exemption from registration under Rule 144 will not be available for at least two years from the date of receipt of the Shares unless at least one year from the date of receipt (i) a public trading market then exists for the Common Stock of the Company, (ii) adequate information concerning the Company is then available to the public, and (iii) other terms and conditions of Rule 144 are complied with; and that any sale of the Shares may be made only in limited amounts in accordance with such terms and conditions and that after ninety days after the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Shares may be resold by persons other than affiliates in reliance on Rule 144 without compliance with paragraphs (c), (d), (e) and (h) thereof, and by affiliates without compliance with paragraph (d) thereof.

(f) Knowledge of Company, Company Information. Purchaser is familiar with the Company, the nature of its business, its financial prospects and the merits and risks of an investment in the Company, and has the capacity to protect its own interests. Purchaser has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company. Purchaser has also had the opportunity to ask questions of, and receive answers from, the Company and its management regarding the terms and conditions of this investment.

(g) Additional Capital. Purchaser understands that the Company may need to raise additional financing to support expansion, develop new or enhanced applications and services, respond to competitive pressures, acquire complementary business or technologies or take advantage of unanticipated opportunities. Purchaser understands that the Company may need to raise additional funds by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Purchaser understands that such financing may be dilutive to existing stockholders.

5. Purchaser's Right of First Refusal.

(a) Right of First Refusal. The Company hereby grants to Purchaser, on the terms set forth in this Section 5, the right of first refusal to purchase all or any part of such Purchaser's pro rata share of the New Securities (as defined in Section 5(b) which the Company may, from time to time,

propose to sell and issue. The Purchaser may purchase said New Securities on the same terms and at the same price at which the Company proposes to sell the New Securities. For the purposes of this right of first refusal, an Purchaser's pro rata share of the New Securities is a fraction, the numerator of which is the total number of shares of Common Stock held by such Purchaser (on an as converted basis) and the denominator of which is the total number of shares of the Company's Common Stock outstanding (including any shares of Common Stock issuable upon conversion of or exercise of, as the case may be, Preferred Stock, options, warrants or other convertible securities) immediately prior to the issuance of the New Securities.

(b) New Securities. "New Securities" shall mean any capital stock of the Company, whether now authorized or not, and any rights, options or warrants to purchase said capital stock, and securities of any type whatsoever that are, or may become, convertible into said capital stock; provided that New Securities does not include (i) the Shares, (ii) Common Stock issued upon conversion of the Company's Preferred Stock, (iii) securities offered pursuant to a registration statement filed under the Act, (iv) securities issued pursuant to a merger, consolidation, strategic alliance, acquisition or similar business combination, (v) securities issued or issuable to officers, directors, employees, advisors, consultants or service providers of the Company pursuant to any plan or arrangement approved by the Board of Directors of the Company, (vi) securities issued pursuant to agreements to license technology and/or provide sponsored research approved by the Board of Directors of the Company (vii) securities issued in connection with equipment leasing or equipment financing, real property leasing or loan arrangement or debt financing from a bank or similar financial or lending institution arrangements approved by the Board of Directors of the Company, (viii) shares of Common Stock issued in connection with any stock split, stock dividend or recapitalization by the Company and (ix) securities issued in connection with strategic transactions involving the Company and other entities, including (a) joint ventures, manufacturing, marketing or distribution arrangement or (b) technology transfer or development arrangements.

(c) Notice of Proposed Issuance. In the event the Company proposes to undertake an issuance of New Securities, it shall give to the Purchaser written notice (the "Notice") of its intention, describing the type of New Securities, the price, the terms upon which the Company proposes to issue the same, the date of the proposed issuance and a statement as to the number of days from receipt of such Notice within which the Purchaser must respond to such Notice. The Purchaser shall have fifteen (15) days from the date of receipt of the Notice to purchase any or all of its pro rata share (as defined in Section 5(a) above) of the New Securities for the price and upon the terms specified in the Notice by giving written notice to the Company and stating therein the quantity of New Securities to be purchased and forwarding payment for such New

Securities to the Company if immediate payment is required by such terms, or in any event no later than the date of the proposed issuance as set forth in the Notice.

(d) Transferability of Right of First Refusal. The right of first refusal granted under this Section 5 may be assigned by the Purchaser to a transferee or assignee (a "Transferee") in connection with any transfer or assignment of at least 50,000 Shares to any parent corporation or entity, subsidiary or affiliate of the Purchaser.

(e) Termination of Rights. The right of first refusal granted under this Section 5 shall expire upon the closing of the Company's first firm commitment underwritten public offering pursuant to an effective registration statement filed by the Company under the Act.

6. Registration Rights.

(a) Company Obligation. If the Company shall determine to register any of its securities either for its own account or the account of a shareholder(s) exercising demand registration rights, other than a registration relating solely to employee benefit plans, or a registration relating solely to a transaction pursuant to Rule 145 promulgated under the Act or a registration on any registration form which does not permit secondary sales or does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Shares, the Company will promptly give the Purchaser written notice thereof and include in such registration (and any related qualification under blue sky laws), and in any underwriting involved therein, the number of shares specified in a written request made by the Purchaser within fifteen (15) days after receipt of such written notice from the Corporation, except as set forth in Section 6(b) below.

(b) Underwritten Public Offering. If the registration for which the Company gives notice is for a registered public offering involving an underwriting, the right of Purchaser to registration shall be conditioned upon the Purchaser's participation in such underwriting and the inclusion of such Purchaser's Shares in the underwriting pursuant to an underwriting agreement in customary form with the underwriter or underwriters selected by the Company. Notwithstanding any other provision of this Section, if the underwriter reasonable determines that marketing factors require a limitation on the number of shares to be underwritten and underwriter may exclude some or all of the Shares with the number of shares that may be included in the registration and underwriting being allocated among the Purchaser and all other shareholders entitled to have securities included in such registration in proportion, as nearly as practicable, to the respective amounts of securities which they had requested to be included in such registration.

(c) Expenses. All expenses of the registration including the expense of one attorney for the selling shareholders (such attorney's expense not to exceed $15,000) shall be borne by the Company, except underwriting discounts and selling commissions applicable to the sale of any Purchaser's Shares and any other securities of the Corporation being sold in the same registration by other shareholders, which shall be borne by the Purchaser and such other shareholders pro rata on the basis of the number of their shares registered.

(d) Transferability of Registration Rights. The registration rights granted under this Section 6 may be assigned by the Purchaser to a Transferee in connection with any transfer or assignment of at least 50,000 Shares to any parent corporation or entity, subsidiary or affiliate of the Purchaser.

(e) Termination of Registration Rights. The registration rights granted under this Section 6 shall terminate as to the Purchaser or a Transferee (a "Holder") when such Holder is eligible to sell all of its shares that can be registered under this Agreement within any 90 day period in reliance on Rule 144 under the Act.

7. Financial Information. The Company will provide the Purchaser with reports and provide access for Purchaser as set forth below.

(a) As soon as practicable after the end of each fiscal year, and in any event within one hundred twenty (120) days thereafter, consolidated balance sheets of the Company and its subsidiaries, if any, as of the end of such fiscal year, and unaudited consolidated statements of income and consolidated statements of changes in financial position of the Company and its subsidiaries, if any, for such year, prepared in accordance with generally accepted accounting principles and setting forth in each case in comparative form the figures for the previous fiscal year (or, at the election of the Company, setting forth in comparative form the budgeted figures for the fiscal year then reported), all in reasonable detail.

(b) As soon as practicable after the end of each quarter, and in any event within sixty (60) days after each quarterly accounting period, an unaudited quarterly report including a balance sheet, profit and loss statement and cash flow analysis (prepared in accordance with generally accepted accounting principles other than for accompanying notes and subject to changes resulting from year-end audit adjustments).

(c) The Company shall permit each Purchaser, at such Purchaser's expense, to visit and inspect the Company's properties, to examine its books of account and records and to discuss the Company's affairs, finances and accounts with its officers, all at such reasonable times as may be requested by the Investor.

(d) Anything in Section 7(c) to the contrary notwithstanding, the Purchaser or transferee of the Purchaser by reason of this Agreement shall not have access to any trade secrets or classified information of the Company. The Purchaser hereby agrees to hold in confidence and trust and not to misuse or disclose any confidential information provided pursuant to Section 7(c) and any transferee of must agree, in writing, to the same. The Company shall not be required to comply with this Section 7(c)in respect of the Purchaser or transferee of the Purchaser whom the Company reasonably determines to be a competitor or an officer, employee, director or greater than 5% shareholder of a competitor or to the extent compliance would result in disclosure of trade secrets.

(e) Termination of Covenants. The covenants set forth in this Section 7 shall terminate and be of no further force or effect upon the closing of the Company's initial underwritten public offering pursuant to an effective registration statement filed by the Company under the Act.

8. Legends. The share certificate evidencing the Shares issued hereunder shall be endorsed with the following legends (in addition to any legend required under applicable state securities laws):

(a) THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE

OR DISTRIBUTION THEREOF. NO SUCH SALE OR DISPOSITION MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933.

(b) THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS PURSUANT TO THE COMPANY'S BYLAWS. SUCH BYLAW, AMONG OTHER THINGS, RESTRICTS CERTAIN RIGHTS WITH RESPECT TO THE SALE AND TRANSFER OF THE SHARES AND OTHERWISE ENCUMBERS THE SHARES REPRESENTED HEREBY. COPIES OF THE BYLAWS MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE COMPANY.

(c) Any legend required to be placed thereon by the Delaware Commissioner of Corporations or any other applicable state securities laws.

9. Restrictions on Transfer.

(a) Without in any way limiting the foregoing, Purchaser further agrees that Purchaser shall in no event make any disposition of all or any portion of the Shares which Purchaser is being issued unless and until: (i) there is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement; or (ii) (A) The transferee has agreed in writing to be bound by the terms of this Agreement, (B) Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and (C) if reasonably requested by the Company, Purchaser shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of the Shares under the Act. In addition, Purchaser agrees that any such disposition shall be made in accordance with the provisions of the Company's Bylaws, provided however that the Company hereby waives any right of first refusal pursuant to Article XIV of the Company's Bylaws with respect to any transfer of the Shares by Purchaser to any parent corporation or entity, subsidiary or affiliate of Purchaser.

(b) The Company shall not be required (i) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in the Section 9(a) or (ii) to treat as owner of such Shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Shares shall have been so transferred.

(c) Purchaser hereby agrees that for a period of not less than 180 days following the effective date of the first registration statement of the Company covering Common Stock (or other securities) to be sold on its behalf in an underwritten public offering, Purchaser shall not, to the extent requested by the Company or any underwriter, sell or otherwise transfer or dispose of (other than to donees who agree to be similarly bound) any Common Stock of the Company held by Purchaser at any time during such period except Common Stock included in such registration.

(d) In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Common Stock held by Purchaser (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

10. Adjustment for Stock Split. All references to the number of Shares and the purchase price of the Shares in this Agreement shall be appropriately adjusted to reflect any stock split, stock dividend or other change in the Shares which may be made by the Company after the date of this

Agreement.

11. Tax Consequences. The Purchaser has reviewed with the Purchaser's own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. The Purchaser is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Purchaser understands that the Purchaser (and not the Company) shall be responsible for the Purchaser's own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

12. General Provisions.

(a) This Agreement shall be governed by the laws of the State of Delaware. This Agreement represents the entire agreement between the parties with respect to the purchase of Common Stock by the Purchaser and may only be modified, amended or waived in writing signed by both parties.

(b) Any notice, demand or request required or permitted to be given by either the Company or the Purchaser pursuant to the terms of this Agreement shall be in writing and shall be deemed given when delivered personally or deposited in the U.S. Mail, First Class with postage prepaid, and addressed to the parties at the addresses of the parties set forth at the end of this Agreement or such other address as a party may request by notifying the other in writing.

(c) Except as otherwise provided herein, the provisions hereof shall inure to the benefit of, and be binding upon, the successors and assigns of the parties, hereto.

(d) Either party's failure to enforce any provision or provisions of this Agreement shall not in any way be construed as a waiver of any such provision or provisions, nor prevent that party thereafter from enforcing each and every other provision of this Agreement. The rights granted both parties herein are cumulative and shall not constitute a waiver of either party's right to assert all other legal remedies available to it under the circumstances.

(e) The Purchaser agrees upon request to execute any further documents or instruments necessary or desirable to carry out the purposes or intent of this Agreement.

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the day and year first set forth above.

COMPANY	**PURCHASER**
NEWLINK GENETICS CORPORATION a Delaware corporation	STODDARD CANCER RESEARCH INST. a d.b.a. of Central Iowa Health System
/s/Charles Link, Jr. (Signature)	/s/ Eric Crowell (Signature)
Charles Link, Jr. (Print Name)	Eric Crowell (Print Name)
Chairman (Title)	President (Include Title if signing on behalf of an entity)
2901 S. Loop Drive (Address)	1200 Pleasant St. (Address)
Ames, IA 50010 (City, State Zip)	Des Moines, IA 50309 (City, State Zip)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Technology Transfer Center
Executive Plaza South, Room 450
6120 Executive Blvd. MSC 7182
Bethesda MD 20892-7182
(301) 496-0477
(301) 402-2117 Fax

May 7, 2007

Dr. Charles Link
NewLink Genetics Corporation
Suite 3900
2901 South Loop Drive
Ames, IA 50010 USA

Re: Letter of Intent for a Cooperative Research and Development Agreement #02166 NCI Principal Investigators: Drs. Sherry S. Ansher, Lee Jia and Howard Streicher Collaborator Investigators: Drs. Charles Link and Nicholas Vahanian
Title: Preclinical and Clinical Development of 1-Methyl [d]-tryptophan as an Anticancer Agent

Dear Dr. Link:

It is my understanding that a cooperative research and development project between the parties referenced below is being considered. Accordingly, until the formal Cooperative Research and Development Agreement (CRADA) is reviewed by the CRADA Subcommittee and approved by the Director, National Cancer Institute (NCI), this Letter is offered to permit the joint research to commence. However, in the case of human clinical trials which are a part of the subject CRADA, the parties agree that all such trials which may begin prior to the execution of the formal CRADA shall be preceded by the appropriate regulatory approvals (U.S. Food and Drug Administration IND approval or international equivalents thereof).

It is acknowledged by the parties below that cooperative research pursuant to the Research Plan, attached as Appendix A, will be conducted informally by the NCI Principal Investigators and Collaborator pending formal approval of the CRADA. It is further acknowledged that patentable inventions may be made by NCI employees and employees of the Collaborator. Pursuant to its authority under the Federal Technology Transfer Act of 1986, as amended, NCI agrees that should this CRADA be approved, it will have retroactive effect to the date that the last party has executed this Letter for any inventions that may be made under this Research Plan. NCI further agrees that should this CRADA be approved it will have retroactive effect to the date that the last party has executed this Letter for confidentiality obligations specified in the NIH Model CRADA. The Model CRADA for Extramural-PHS Clinical Research (2005) provisions for the protection of proprietary information are incorporated in this Letter by reference and are considered controlling during the period of informal joint research. These provisions include, but

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are not limited to Articles 2.0 and 8. The Model CRADA for Extramural-PHS Clinical Research (2005) is attached as Appendix B and the CTEP Exceptions or Modifications to this CRADA (6/27/06) is attached as Appendix C.

You understand, however, that this Letter is not a commitment on the part of either party to enter into a CRADA. Further, this Letter is effective for a term not to exceed six (6) months. The six month term may be extended, provided the CRADA is under active negotiation and the collaborative research is continuing. Assuming that the necessary approvals are forthcoming, we look forward to a successful collaboration.

Sincerely,

/s/ Kathleen Carroll for
Karen Maurey, M.S.
Chief, Technology Transfer Center, NCI

AGREED AND ACCEPTED:

National Cancer Institute

/s/Anna D. Barker
Anna D. Barker, Ph.D.
Deputy Director

05/14/07
Date

NewLink Genetics Corporation

/s/ Charles Link

05/23/07
Date

Attachments: Appendix A - Letter of Intent Research Plan

Appendix A

Letter of Intent Research Plan

Letter of Intent for Proposed CRADA #2166

APPENDIX A: LETTER OF INTENT RESEARCH PLAN

Pre-Clinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent

National Cancer Institute (NCI) Investigators:
Dr. Sherry Ansher
Dr. Lee Jia
Dr. Howard Streicher

NewLink Genetics Corporation Investigators:
Dr. Charles Link
Dr. Nicholas Vahanian

Term of Proposed CRADA:
Four (4) years from the date of CRADA execution

1. RESEARCH GOALS OF PROPOSED CRADA

The overall goal of this proposed CRADA is to collaborate with NewLink Genetics Corporation (hereafter NewLink) on the pre-clinical and clinical development of 1-methyl-D-tryptophan (also known as 1MT, NSC721782, or Investigational Agent) for the treatment of cancers that overexpress indoleamine 2,3-dioxygenase (IDO) and other cancers in which IDO plays a critical immunological role.

The Division of Cancer Treatment and Diagnosis (DCTD), NCI and NewLink will both provide resources and expertise for the pre-clinical development of 1MT and will work together towards the successful clinical development of 1MT as a safe and effective novel pharmaceutical compound. The DCTD will provide expertise in designing, implementing and monitoring Phase 0, Phase 1 and Phase 2 clinical trials through its intramural and extramural clinical trials network. Additionally, the DCTD will work jointly with NewLink to obtain all the necessary regulatory approval by the U.S. Food and Drug Administration (FDA) for 1MT as an anti-cancer agent. NewLink will provide expertise in the development, formulation and production of 1MT. The Parties will work together in the design, implementation and monitoring of the clinical trials planned under this CRADA as well as all regulatory aspects and New Drug Application (NDA) filings as necessary for marketing approval for 1MT as an anti-cancer agent.

2. SCIENTIFIC BACKGROUND

The enzyme IDO catalyzes tryptophan degradation. IDO can be a potent effector of immunosuppression and of tolerance induction in certain settings; for example, expression of IDO in the placenta maintains maternal tolerance towards the fetus. Tumors create a state of immunologic unresponsiveness (tolerance) toward their own antigens, which allows tumors to escape the host's immune system. This also imposes a barrier to effective anti-tumor immunotherapy. One molecular mechanism contributing to this tolerance is expression of the immunosuppressive enzyme IDO, leading to inhibition of T-cell response.

Expression of IDO by human and mouse antigen-presenting cells inhibits T cell mediated immune responses *in vitro* and *in vivo*. Tumor cells transfected with IDO become immunosuppressive *in vivo*, and expression of IDO has been reported in tumor cells from a variety of human tumors. IDO is also expressed by a population of host antigen-presenting cells (dendritic cells) found in tumor-draining lymph nodes of melanoma, breast cancer, and a variety of other tumors, which may act to create tolerance to tumor antigens. Therefore, IDO may be a primary molecular target for cancer immunotherapy and inhibition of the IDO pathway may assist in breaking tumor tolerance.

Studies have shown that the small-molecule 1MT possesses immune-enhancing activity by inhibiting IDO in a variety of animal models. 1MT can inhibit IDO enzyme activity *in vitro* and can prevent IDO-mediated immunosuppression *in vivo*. 1MT has also been shown to be synergistic with a number of commonly used chemotherapeutic agents. Thus, 1MT may potentially be used as a novel immune modulator in cancer immunotherapy.

3. PRE-CLINICAL DEVELOPMENT OF 1MT

1MT was originally submitted to the NCI's Rapid Access to Intervention Development (RAID) program by Dr. David Munn, Medical College of Georgia, and Dr. Scott Antonia, H. Lee Moffitt Cancer Center, and the application was approved by NCI in April 2001. Based upon promising *in vitro* and *in vivo* data, 1MT was then reviewed by the NCI's Drug Development Group (DDG) and was approved by the DDG in December 2003 for further pre-clinical development at DDG level IIA. In January 2006 the DDG approved 1MT at level IIB/III to start IND-directed toxicology studies and to

subsequently enter into NCI sponsored clinical trials. In October 2005, University of Georgia granted NewLink a worldwide, exclusive license to patents covering therapeutic uses of 1MT as an immunomodulator for any and all medical applications.

The following sections summarize the pre-clinical studies conducted by the NCI prior to this CRADA Letter of Intent.

[*]

4. BACKGROUND OF THE COLLABORATOR

NewLink is a biopharmaceutical company applying innovative techniques in cancer biology to produce new diagnostic and therapeutic agents for cancer patients. NewLink is privately held and was incorporated in June 1999. The core of NewLink is a Cancer Vaccine Development Division that exists to accelerate the deployment of oncology pharmaceuticals, including HyperAcute™ Vaccines, into clinical testing and commercialization. NewLink has recently acquired a worldwide, exclusive license to patents covering therapeutic uses of 1MT as [*] for [*], and its OncoRx Division undertakes the development 1MT. 1MT is envisioned as [*] and as an adjuvant therapy for use in combination with immuno-modulating therapies for the purpose of enhancing the effects of the immuno-modulating therapy. NewLink expects to start 1MT Phase 1 and Phase 2 clinical trials in [*], subject to the filing of one or more NewLink-sponsored INDs to support such studies.

5. DETAILED DESCRIPTION OF THE RESEARCH PLAN

The Division of Cancer Treatment and Diagnosis (DCTD), NCI and NewLink are interested in the evaluation of 1MT in a pre-clinical and clinical development program that includes various tumor types that over-express IDO and other cancers in which IDO plays a critical immunological role. The pre-clinical work will include IND-directed toxicology studies and formulation studies. In addition, if NCI deems it necessary, NCI may conduct pre-clinical research aimed at enhancing the understanding of the mechanism of action of 1MT and its targets and optimizing its clinical development program. NCI's work may also include such activities as the development of assays to detect target modulation, biomarker studies, and pharmacodynamic analyses performed in conjunction with the DCTD-sponsored clinical studies. DCTD will sponsor 1MT Phase 0, Phase 1 and Phase 2 clinical trials that will help determine the safety, efficacy and the potential spectrum of 1MT's anti-tumor activity. DCTD and NewLink are also interested in evaluating 1MT in combination with other novel investigational agents or cancer therapeutics such as vaccines, chemotherapy and radiation therapy in clinical trials.

6. RESPECTIVE CONTRIBUTIONS OF THE PARTIES

A. Joint Responsibilities

1. Steering Committee and Communication Plan

A Steering Committee will be employed by the Parties to exchange information and data and to discuss and to plan the proposed and ongoing clinical research. The Steering Committee shall be composed of the CRADA Principal Investigators from NCI and NewLink. In addition, other NCI and NewLink staff with expertise in toxicology, pharmacology, pharmaceutical development, project management and other disciplines as pertinent to the current development stage of the Investigational Agent at the time of a meeting may participate in the meetings of the Steering Committee. Both Parties shall report regularly to the Steering Committee on the progress of the clinical research and development efforts covered by this CRADA, will review the current progress, and will make any required decisions. The routes of communication, format of written minutes, etc. will be determined at the Steering Committee meetings and will be driven by the needs of the project. The Parties have been meeting regularly prior to the execution of this CRADA Letter of Intent, and will continue to do so.

The Steering Committee will function under the oversight of Co-Chairs, one from NCI and one from the Collaborator. NCI's Steering Committee Co-Chair will be appointed by the DCTD Division Director and report to the DCTD Division Director or his or her designee. Steering Committee meeting minutes summarizing all key decisions and issues under discussion will be provided to all the Steering Committee members and to the DCTD Division Director within [*] of each meeting. Steering Committee decisions will be made [*].

2. DCTD's preclinical and ancillary studies shall be conducted [*], as per [*].

3. The DCTD and NewLink will explore the clinical utility of 1MT for various cancers. As sensitive tumor types are identified, it will be important to develop combinations of 1MT and other active anti-cancer agents and to compare 1MT and 1MT combinations with standard therapy for these tumor types. Adjuvant studies may be important in diseases where 1MT has activity and where there is a high risk of recurrence following initial primary therapy.

4. Both Parties shall collaborate in the collection and analysis of data generated under the Research Plan.

5. Both Parties will work closely together to ensure that the pre-clinical and clinical studies move forward expeditiously.

6. Subject to the obligations of the Parties to maintain the data under this CRADA as confidential and proprietary, the Parties may publicly disclose the results of their research under the circumstances set forth in the model CRADA.

7. When pre-clinical studies and/or a CRADA clinical protocol involves either [*] or involves [*], the NCI, NewLink [*] will jointly determine a reasonable and appropriate mechanism for intellectual property and data access and sharing prior to initiation of the pre-clinical studies and/or the clinical trial.

8. For activities conducted pursuant to this CRADA in the United States of America, both Parties agree to comply with all appropriate DHHS regulations relating to Human Subjects Use, all U.S. Department of Agriculture regulations, and all Public Health Service policies relating to the use and care of laboratory animals. For activities conducted pursuant to this CRADA outside of the United States of America, both Parties shall conduct such in accordance with GLPs and all applicable rules, regulations and statutes, both local and national, governing such activity in that country.

9. The Parties acknowledge that [*] means any [*] that is either readily usable as a [*] or is [*] that will be useful to [*] in developing [*] (rather than useful [*] or [*]). A [*] may simultaneously be a [*] and be the essence of a [*], or [*] (or an integral component of such [*]). For the purposes of this CRADA, [*] shall include, but not be limited to, a [*]. If NewLink elects to request [*] that is a [*], such [*] will ensure, as appropriate for the circumstances, that (a) the [*] will undertake to make the [*] on a [*] to [*] for [*] under [*], such [*], or (b) [*] the right to make the [*] on a [*] to [*] for [*] purposes under [*].

B. NewLink Responsibilities

1. Following execution of the CRADA, NewLink will provide [*] funding for pre-clinical studies including the IND-directed toxicity studies and formulation studies which will be conducted by [*]. The exact amount of funding and the payment schedule will be agreed upon and addressed in an Appendix B to the executed CRADA.

2. Following CRADA execution, NewLink will be responsible for the [*] cost of GMP-grade 1MT in current [*] inventories manufactured to support pre-clinical studies, NCI-sponsored [*] clinical trials, and NewLink-sponsored [*] clinical trials. The exact amount of funding and the payment schedule will be agreed upon and addressed in an Appendix B to the executed CRADA.

   If additional formulated 1MT is required for clinical studies under this CRADA Research Plan, NewLink will be responsible for the provision and costs of such extra supply of formulated and acceptably labeled 1MT. NewLink may elect to produce bulk 1MT and formulated 1MT through contractors other than established [*] contractors in order to obtain the most competitive pricing. NewLink will then be responsible for subsequent payment of such contractors, and [*] will have no obligations with respect to such contractors. If NewLink elects to perform any portion of this CRADA Research Plan through a contractor or consultant, NewLink shall incorporate into such contracts all provisions necessary to ensure that the work of the contractor or consultant is governed by the terms of the CRADA, including, but not limited to, a provision for the assignment of inventions of the contractor or consultant to NewLink; such inventions shall be deemed [*] of NewLink. In addition, NewLink will ensure that any contractor or consultant is obligated to maintain [*] Confidential Information regarding 1MT manufacturing and formulation in confidence at least to the extent provided for by the terms of the CRADA.

   Following the use of [*] supplies of 1MT, NewLink will provide 1MT to [*] for use by [*] in [*] studies, studies designed to [*] of 1MT, and other studies relevant to the development of 1MT as provided in the Research Plan.

3. NewLink will prepare and submit to the FDA an Investigational New Drug Application (IND) for NewLink sponsored clinical studies of 1MT, which will cross-reference the DCTD IND.

4. NewLink agrees to permit DCTD to supply formulated 1MT for all clinical trials set forth in this CRADA. This includes:

   · Provision of appropriately packaged and labeled 1MT for all NCI-sponsored clinical studies;

   · Supply of 1MT for compassionate use, as described in the NCI Investigator Handbook; and

   · Supply of 1MT for, and any resources necessary for the management of, Group C distribution, as described in the NCI Investigator Handbook. Group C distribution shall be initiated if such action is justified by clinical results and is feasible based on adequate 1MT supply, such that NewLink's NDA efforts are not negatively impacted.

   NewLink agrees to supply 1MT, or to provide unformulated analytical grade 1MT or metabolites, if available, to DCTD for DCTD to provide to DCTD intramural and extramural investigators for the development of analytical assays or ancillary

correlative studies conducted in conjunction with DCTD-approved protocols. NewLink also agrees to provide 1MT for distribution for pre-clinical studies designed to enhance the basic understanding and development of 1MT. These will include pre-clinical studies designed to support clinical trials in [*]; pre-clinical [*] studies to provide data in support of a clinical trial; and other pertinent requests.

5. Upon CRADA execution, NewLink will provide resources for data collection and management, beyond that normally carried out by the DCTD as set forth in the CRADA for CTEP-sponsored studies, if NewLink desires such data collection and management. This would include the collection of the data required to submit an NDA to the FDA.

6. Upon CRADA execution, NewLink may provide funds for partial support of the DCTD-sponsored clinical trials and IND.

7. Upon CRADA execution, NewLink will provide funds for travel by DCTD staff to attend meetings sponsored by NewLink concerning 1MT clinical trials, such funds not to exceed [*] per year of the term of the CRADA.

8. NewLink intends and will use reasonable efforts to prepare and submit an NDA to the FDA expeditiously when justified by clinical studies, with the object of obtaining pharmaceutical regulatory approval for the commercial marketing of 1MT.

9. NewLink may sponsor its own clinical trials using 1MT. Such Collaborator-sponsored trials are outside the scope of this CRADA. For these clinical trials, NewLink will maintain possession and control of the clinical trial results. NewLink will permit DCTD to review and use the results for DCTD-sponsored clinical trials which are under the CRADA.

10. NewLink will update DCTD on the progress of its preclinical studies of 1MT to help ensure optimal experimental designs and avoid duplication.

C. NCI Responsibilities

I. Division of Cancer Treatment and Diagnosis, NCI

1. DCTD will develop and implement its preclinical/pharmacodynamic program for 1MT. DCTD also may conduct [*] studies to [*] 1MT. DCTD will update Collaborator regarding progress and findings to help ensure optimal experimental designs and avoid duplication.

2. DCTD will conduct [*] studies in [*], and [*] studies using existing supplies of 1MT. As stated in B(l) above, upon execution of the CRADA, NewLink will be responsible for partial costs associated with such studies.

3. DCTD will provide GMP-grade 1MT for [*] Phase 0 clinical studies, initial [*] Phase 1 clinical studies, and [*] Phase 1 clinical trials. As stated in [*], upon execution of

the CRADA, [*] will be responsible for the costs associated with the drug production for such clinical studies.

4. The DCTD, as sponsor, will prepare and submit to the FDA an IND for 1MT for NCI-sponsored clinical studies. DCTD will permit NewLink to participate in DCTD's IND preparation process.

5. The DCTD will collaborate solely with NewLink for 1MT development, and will assist NewLink in all aspects of the regulatory approval process, so long as NewLink is pursuing clinical development of 1MT.

6. To the extent permitted by law, the DCTD will maintain the DCTD-sponsored IND, including protocols and other supporting information relative to 1MT as an anti-cancer agent in DCTD's possession and control, as proprietary and confidential, and make it available exclusively to NewLink. The DCTD will permit NewLink to review, cross-reference and use the IND in conducting clinical trials and in fulfilling all of the requirements necessary for obtaining FDA approval to market 1MT as an anti-cancer agent.

7. To the extent permitted by law, the DCTD will maintain the clinical data, results and raw data from all new studies developed under this proposed CRADA in its possession and control, as proprietary and confidential, and make them available exclusively to NewLink for use in obtaining approval for the commercial marketing of 1MT as an anti-cancer agent, so long as NewLink is pursuing commercial development for 1MT.

8. The DCTD will solicit protocol Letters of Intent (LOI) from the investigators in the DCTD's clinical trials network as appropriate.

The Protocol Review Committee (PRC), of the DCTD, will:

· Evaluate the rationale of each LOI received at the DCTD;

· Review the LOIs for study design, including dose, schedule and comparison groups, if relevant, in order to address any pertinent scientific questions;

· Examine the characteristics of the patient population to be studied;

· Assess the feasibility of the projected accrual, including the ability of each investigator to accrue the appropriate patient population in a timely manner;

· Review competing studies of the investigator in the specified disease(s);

· Provide investigator(s) with consensus review(s) of the PRC's evaluation to be used to revise the protocol;

· Provide a copy of the consensus review to NewLink. All CTEP approved clinical LOIs will be sent by NCI to NewLink. NewLink will provide NCI with its approval or disapproval within [*] of receiving the CTEP approved clinical LOIs. Only LOIs that have been approved by both the PRC and NewLink will lead to the submission of full study protocols.

The protocols received from investigators in response to the fully approved LOIs will be reviewed and evaluated by the PRC and by NewLink. The PRC will:

· Evaluate each protocol from agent, disease, statistical and regulatory perspectives in order to ensure that the study design that was approved by the PRC at the LOI stage is carried out.

· Provide each clinical research protocol received by DCTD to NewLink for review and comment approximately [*] before it is reviewed by the PRC of CTEP. Comments from NewLink received by CTEP before the PRC meeting will be discussed by the PRC, will be

given due consideration, and will be incorporated into the protocol, absent good cause. Comments from either NewLink or the CTEP staff that are agreed upon in the PRC meeting will be formatted as a consensus review, which is returned to the investigator for necessary and/or suggested changes before the protocol can be given final approval and submitted to the FDA. In addition, the PRC will review any correlative laboratory studies, solicited from investigators, to address cellular pharmacological and/or pharmacokinetics questions as necessary.

9. The DCTD will evaluate each of the active studies as they progress to ensure that the appropriate questions are being addressed and to ensure that the studies are modified as required based on the developing data. The DCTD will utilize its existing procedures and mechanisms to follow the clinical studies to ensure that all studies meet the pertinent FDA regulations.

II. Experimental Immunology Branch, Center for Cancer Research, NCI

[*] studies such as [*] in [*] will be conducted in the Experimental Immunology Branch under the direction of Dr. Gene Shearer.

7. Intellectual Property of the Parties:

NCI Patents and Patent Applications: [*]

NewLink has obtained a worldwide, exclusive license to the following patents covering [*] for [*] from the University of Georgia.

[*]

In addition, a number of patent applications corresponding to the above patent applications and patents have been filed in countries other than the U.S.

Appendix B

NIH Model CRADA for Extramural-PHS Clinical Research (version 2005)

PUBLIC HEALTH SERVICE

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
FOR EXTRAMURAL-PHS CLINICAL RESEARCH

This Agreement is based on the model Cooperative Research and Development Agreement ("CRADA") adopted by the U.S. Public Health Service ("PHS") Technology Transfer Policy Board for use by components of the National Institutes of Health ("NIH"), the Centers for Disease Control and Prevention ("CDC"), and the Food and Drug Administration ("FDA"), which are agencies of the PHS within the Department of Health and Human Services ("HHS").

This Cover Page identifies the Parties to this CRADA:

The U.S. Department of Health and Human Services, as represented by
[Insert the full name of the ICD]
an Institute, Center, or Division (hereinafter referred to as the "ICD") of the
[INSERT as appropriate: NIH, CDC, or FDA]

and

[Insert Collaborator's official name],
hereinafter referred to as the "Collaborator",
having offices at **[Insert Collaborator's address**],
created and operating under the laws of **[Insert State of Incorporation]**.

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
FOR EXTRAMURAL-PHS CLINICAL RESEARCH

Article 1. Introduction

This CRADA between ICD and Collaborator will be effective when signed by the Parties, which are identified on both the Cover Page and the Signature Page (page 22). The official contacts for the Parties are identified on the Contacts Information Page (page 23). Publicly available information regarding this CRADA appears on the Summary Page (page 24). The research and development activities that will be undertaken by ICD, ICD's contractors or grantees, and Collaborator in the course of this CRADA are detailed in the Research Plan, attached as Appendix A. The staffing, funding, and materials contributions of the Parties are set forth in Appendix B. Any changes to the model CRADA are set forth in Appendix C.

Article 2. Definitions

The terms listed in this Article will carry the meanings indicated throughout the CRADA. To the extent a definition of a term as provided in this Article is inconsistent with a corresponding definition in the applicable sections of either the United States Code (U.S.C.) or the Code of Federal Regulations (C.F.R.), the definition in the U.S.C. or C.F.R. will control.

"**Adverse Drug Experience**" or "**ADE**" means an Adverse Event associated with the use of the Test Article, that is, an event where there is a reasonable possibility that the Test Article may have caused the event (a relationship between the Test Article and the event cannot be ruled out), in accordance with the definitions of 21 C.F.R. Part 310, 305, or 312, or other applicable regulations.

"**Adverse Event**" or "**AE**" means any untoward medical occurrence in a Human Subject administered Test Article. An AE does not necessarily have a causal relationship with the Test Article, that is, it can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the Test Article, whether or not it is related to it. See FDA Good Clinical Practice Guideline (International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance, 62 Federal Register 25, 691 (1997)).

"**Affiliate**" means any corporation or other business entity controlled by, controlling, or under common control with Collaborator at any time during the term of the CRADA. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock or at least fifty percent (50%) interest in the income of the corporation or other business entity.

"**Annual Report**" means the report of progress of an IND-associated investigation that the Sponsor must submit to the FDA within sixty (60) days of the anniversary of the effective date of the IND (pursuant to 21 C.F.R. § 312.33).

"**Background Invention**" means an Invention conceived and first actually reduced to practice before the Effective Date.

"**Clinical Data in ICD's Possession and Control**" means all Raw Data that ICD employees create directly; and all copies of Raw Data and Summary Data that ICD obtains from Clinical Investigators or contractors performing CRADA activities.

"**Clinical Investigator**" means, in accordance with 21 C.F.R. § 312.3, an individual who actually conducts a clinical investigation, that is, who directs the administration or dispensation of Test Article to a subject, and who assumes responsibility for studying Human Subjects, for recording and ensuring the integrity of research data, and for protecting the welfare and safety of Human Subjects.

"**Clinical Research Site(s)**" means the site(s) at which the Protocol(s) described in the Research Plan will be performed.

"**Collaborator Materials**" means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by Collaborator and used in the performance of the Research Plan. The term "Collaborator Materials" does not include "Test Article" (defined below).

"**Confidential Information**" means confidential scientific, business, financial information, or Identifiable Private Information provided that Confidential Information does not include:

(a) information that is publicly known or that is available from public sources;

(b) information that has been made available by its owner to others without a confidentiality obligation;

(c) information that is already known by the receiving Party, or information that is independently created or compiled by the receiving Party without reference to or use of the provided information; or

(d) information that relates to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the Research Plan.

"**Cooperative Research and Development Agreement**" or "**CRADA**" means this Agreement, entered into pursuant to the Federal Technology Transfer Act of 1986, as amended (15 U.S.C. §§ 3710a et seq.), and Executive Order 12591 of April 10, 1987.

"**CRADA Data**" means information developed by or on behalf of the Parties in the performance of the Research Plan, excluding Raw Data.

"**CRADA Materials**" means all tangible materials first produced in the performance of the Research Plan other than CRADA Data.

"**CRADA Principal Investigator(s)**" or "**CRADA PI(s)**" means the person(s) designated by the Parties who will be responsible for the scientific and technical conduct of the Research Plan.

"**CRADA Subject Invention**" means any Invention of either or both Parties, conceived or first actually reduced to practice in the performance of the Research Plan.

"**Drug Master File**" or "**DMF**" is described in 21 C.F.R. Part 314.420. A DMF is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

"**Effective Date**" means the date of the last signature of the Parties executing this Agreement.

"**Government**" means the Government of the United States of America.

"**Human Subject**" means, in accordance with the definition in 45 C.F.R. § 46.102(f), a living individual about whom an investigator conducting research obtains:

(a) data through intervention or interaction with the individual; or
(b) Identifiable Private Information.

"**ICD Materials**" means all tangible materials not first produced in the performance of this CRADA that are owned or controlled by ICD and used in the performance of the Research Plan.

"**IND**" means an "Investigational New Drug Application," filed in accordance with 21 C.F.R. Part 312 under which clinical investigation of an experimental drug or biologic (Test Article) is performed in Human Subjects in the United States or intended to support a United States licensing action.

"**Identifiable Private Information**" or "**IPI**" about a Human Subject means private information from which the identity of the subject is or may readily be ascertained. Regulations defining and governing this information include 45 C.F.R. Part 46 and 21 C.F.R. Part 50.

"**Institutional Review Board**" or "**IRB**" means, in accordance with 45 C.F.R. Part 46, 21 C.F.R. part 56, and other applicable regulations, an independent body comprising medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of the Human Subjects involved in a study.

"**Invention**" means any invention or discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code, or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act, 7 U.S.C. §§ 2321 et seq.

"**Investigator's Brochure**" means, in accordance with the definition in 21 C.F.R. § 312.23(a)(5), a document containing information about the Test Article, including animal screening, preclinical toxicology, and detailed pharmaceutical data, including a description of possible risks and side effects to be anticipated on the basis of prior experience with the drug or related drugs, and precautions, such as additional monitoring, to be taken as part of the investigational use of the drug.

"**Patent Application**" means an application for patent protection for a CRADA Subject Invention with the United States Patent and Trademark Office ("U.S.P.T.O.") or the corresponding patent-issuing authority of another nation.

"**Patent**" means any issued United States patent, any international counterpart(s), and any corresponding grant(s) by a non-U.S. government in place of a patent.

"**Placebo**" means an inactive substance identical in appearance to the material being tested that is used to distinguish between drug action and suggestive effect of the material under study.

"**Protocol**" means the formal, detailed description of a study to be performed as provided for in the Research Plan. It describes the objective(s), design, methodology, statistical considerations, and organization of a trial. For the purposes of this CRADA, the term, Protocol, for clinical research involving Human Subjects, includes any and all associated documents, including informed consent forms, to be provided to Human Subjects and potential participants in the study.

"**Raw Data**" means the primary quantitative and empirical data first collected from experiments and clinical trials conducted within the scope of this CRADA.

"**Research Plan**" means the statement in Appendix A of the respective research and development commitments of the Parties. The Research Plan should describe the provisions for sponsoring the IND, clinical and safety monitoring, and data management.

"**Sponsor**" means, in accordance with the definition in 21 C.F.R. § 312.3, an organization or individual who assumes legal responsibility for supervising or overseeing clinical trials with Test Articles, and is sometimes referred to as the IND holder.

"**Steering Committee**" means the research and development team whose composition and responsibilities with regard to the research performed under this CRADA are described in Appendix A.

"**Summary Data**" means any extract or summary of the Raw Data, generated either by or, on behalf of, ICD or by, or on behalf of, Collaborator. Summary Data may include extracts or summaries that incorporate IPI.

"**Test Article**" means, in accordance with 21 C.F.R. § 50.3(j), any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, including a drug or biologic as identified in the Research Plan and Appendix B, that is used within the scope of the Research Plan. The Test Article may also be referred to as Investigational Agent, Study Material, or Study Product.

Article 3. Cooperative Research and Development

3.1 **Performance of Research and Development.** The research and development activities to be carried out under this CRADA will be performed by the Parties identified on the Cover Page, as well as ICD's contractors or grantees as described in the Research Plan. However, ICD's contractors or grantees

are not Parties to the CRADA, and this CRADA does not grant to Collaborator any rights to Inventions made by ICD's contractors or grantees. The CRADA PIs will be responsible for coordinating the scientific and technical conduct of this project on behalf of their employers. Any Collaborator employees who will work at ICD facilities will be required to sign a Guest Researcher or Special Volunteer Agreement appropriately modified in view of the terms of this CRADA.

3.2 **Research Plan.** The Parties recognize that the Research Plan describes the collaborative research and development activities they will undertake and that interim research goals set forth in the Research Plan are good faith guidelines. Should events occur that require modification of these goals, then by mutual agreement the Parties can modify them through an amendment, according to Paragraph 13.6.

3.3 **Use and Disposition of Collaborator Materials and ICD Materials.** The Parties agree to use Collaborator Materials and ICD Materials only in accordance with the Research Plan and Protocol(s), not to transfer these materials to third parties except in accordance with the Research Plan and Protocol(s) or as approved by the owning or providing Party, and, upon expiration or termination of the CRADA, to dispose of these materials as directed by the owning or providing Party.

3.4 **Third-Party Rights in Collaborator's CRADA Subject Inventions.** If Collaborator has received (or will receive) support of any kind from a third party in exchange for rights in any of Collaborator's CRADA Subject Inventions, Collaborator agrees to ensure that its obligations to the third party are both consistent with Articles 6 through 8 and subordinate to Article 7 of this CRADA.

3.5 **Disclosures to ICD.** Prior to execution of this CRADA, Collaborator agrees to disclose to ICD all instances in which outstanding royalties are due under a PHS license agreement and in which Collaborator had a PHS license terminated in accordance with 37 C.F.R. § 404.10. These disclosures will be treated as Confidential Information upon request by Collaborator in accordance with Paragraphs 2.4, 8.3, and 8.4.

3.6 **Clinical Investigator Responsibilities.** The Clinical Investigator will be required to submit, or to arrange for submission of, each Protocol associated with this CRADA to all appropriate IRBs, and for ensuring that the IRBs are notified of the role of Collaborator in the research. In addition to the Protocol all associated documents, including informational documents and advertisements, must be reviewed and approved by the appropriate IRB(s) before starting the research at each Clinical Research Site. The research will be done in strict accordance with the Protocol(s) and no substantive changes in a finalized Protocol will be made unless mutually agreed upon, in writing, by the Parties. Research will not commence (or will continue unchanged, if already in progress) until each substantive change to a Protocol, including

those required by either the FDA or the IRB, has been integrated in a way acceptable to the Parties, submitted to the FDA (if applicable) and approved by the appropriate IRBs.

3.7 **Investigational Applications.**

3.7.1 If an IND is required either ICD or Collaborator, as indicated in the Research Plan, will submit an IND and all Clinical Investigators must have completed registration documents on file (1572 forms).

3.7.2 If ICD elects to file its own IND, Collaborator agrees to provide ICD background data and information necessary to support the IND. Collaborator further agrees to provide a letter of cross-reference to all pertinent regulatory filings sponsored by Collaborator. Collaborator's employees will be reasonably available to respond to inquiries from the FDA regarding information and data contained in the Collaborator's IND, DMF, other filings, or other information and data provided to ICD by the Collaborator pursuant to this Article 3. If ICD has provided information or data to assist Collaborator in its IND filing, ICD will provide a letter of cross reference to its IND and respond to inquiries related to information provided by ICD, as applicable.

3.7.3 If Collaborator supplies Confidential Information to ICD in support of an IND filed by ICD, this information will be protected in accordance with the corresponding confidentiality provisions of Article 8.

3.7.4 Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this CRADA. These studies, however, should not adversely affect the ability to accomplish the goal of the Research Plan, for example, by competing for the same study population. All data from those clinical trials are proprietary to Collaborator for purposes of this CRADA.

3.8 **Test Article Information and Supply.** Collaborator agrees to provide ICD without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade Test Article (and, as required by the Protocol(s), Placebo) to complete the clinical trial(s) agreed to and approved under this CRADA. Collaborator will provide a Certificate of Analysis to ICD for each lot of the Test Article provided.

3.9 **Test Article Delivery and Usage.** Collaborator will ship the Test Article and, if required, Placebo to ICD or its designee in containers marked in accordance with 21 C.F.R. § 312.6. ICD agrees that the Clinical Investigators will keep appropriate records and take reasonable steps to ensure that the Test Article is used in accordance with the Protocol(s) and applicable FDA regulations. In addition, ICD agrees that the Test Article (and all Confidential Information supplied by Collaborator relating to the Test Article) will be used solely for the conduct of the CRADA research and development activities. Furthermore, ICD agrees that no analysis or modification of the Test Article will be performed without Collaborator's prior written consent. At the completion of the Research Plan, any unused quantity of Test Article will be returned to Collaborator or disposed as directed by Collaborator. Pharmacy contacts at ICD or its designee will be determined by ICD and communicated to Collaborator.

3.10 **Monitoring.**

3.10.1 The Sponsor or its designee will be primarily responsible for monitoring clinical sites and for assuring the quality of all clinical data, unless otherwise stated in the Research Plan. Monitoring will comply with FDA Good Clinical Practice (International Conference on

Harmonisation (ICH) E6: “Good Clinical Practice: Consolidated Guidance; 62 Federal Register 25, 691 (1997)). The other Party may also perform quality assurance oversight. The monitor will communicate significant Protocol violations and submit documentation of monitoring outcomes on Protocol insufficiencies to the other Party in a timely manner.

3.10.2 Subject to the restrictions in Article 8 concerning IPI, and with reasonable advance notice and at reasonable times, ICD will permit Collaborator or its designee(s) access to clinical site(s) to monitor the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical Practice and the Protocol(s).

3.11 **FDA Meetings/Communications.** All meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and to participate in these meetings. The Sponsor will provide the other Party with copies of FDA meeting minutes, all transmittal letters for IND submissions, IND safety reports, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to the INDs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.

Article 4. Reports

4.1 **Interim Research and Development Reports.** The CRADA PIs should exchange information regularly, in writing. This exchange may be accomplished through meeting minutes, detailed correspondence, circulation of draft manuscripts, Steering Committee reports, copies of Annual Reports and any other reports updating the progress of the CRADA research. However, the Parties must exchange updated Investigator’s Brochure, formulation and preclinical data, and toxicology findings, as they become available.

4.2 **Final Research and Development Reports.** The Parties will exchange final reports of their results within six (6) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications.

4.3 **Fiscal Reports.** If Collaborator has agreed to provide funding to ICD under this CRADA and upon the request of Collaborator, then concurrent with the exchange of final research and development reports according to Paragraph 4.2, ICD will submit to Collaborator a statement of all costs incurred by ICD for the CRADA. If the CRADA has been terminated, ICD will specify any costs incurred before the date of termination for which ICD has not received funds from

Collaborator, as well as for all reasonable termination costs including the cost of returning Collaborator property or removal of abandoned Collaborator property, for which Collaborator will be responsible.

4.4 **Safety Reports.** In accordance with FDA requirements, the Sponsor will establish and maintain records and submit safety reports to the FDA, as required by 21 C.F.R. § 312.32 and 21 C.F.R. 812.150(b)(1), or other applicable regulations. In the conduct of research under this CRADA, the Parties will comply with specific ICD guidelines and policies for reporting ADEs and AEs, as well as procedures specified in the Protocol(s). The Sponsor must provide the other Party with copies of all Safety Reports concurrently with their submission to the FDA, and with any other information affecting the safety of Human Subjects in research conducted under this CRADA.

4.5 **Annual Reports.** The Sponsor will provide the other Party a copy of the Annual Report concurrently with the submission of the Annual Report to the FDA. Annual Reports will be kept confidential in accordance with Article 8,

Article 5. Staffing, Financial, and Materials Obligations

5.1 **ICD and Collaborator Contributions.** The contributions of any staff, funds, materials, and equipment by the Parties are set forth in Appendix B. The Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a(d)(1) prohibits ICD from providing funds to Collaborator for any research and development activities under this CRADA.

5.2 **ICD Staffing.** No ICD employees will devote 100% of their effort or time to the research and development activities under this CRADA. ICD will not use funds provided by Collaborator under this CRADA for ICD personnel to pay the salary of any permanent ICD employee. Although personnel hired by ICD using CRADA funds will focus principally on CRADA research and development activities, Collaborator acknowledges that these personnel may nonetheless make contributions to other research and development activities, and the activities will be outside the scope of this CRADA.

5.3 **Collaborator Funding.** Collaborator acknowledges that Government funds received by Collaborator from an agency of the Department of Health and Human Services may not be used to fund ICD under this CRADA. If Collaborator has agreed to provide funds to ICD then the payment schedule appears in Appendix B and Collaborator will make payments according to that schedule. If Collaborator fails to make any scheduled payment, ICD will not be obligated to perform any of the research and development activities specified herein or to take any other action required by this CRADA until the funds are received. ICD will use these funds exclusively for the purposes of this CRADA. Each Party will maintain separate and distinct current accounts, records, and other evidence supporting its financial obligations under this CRADA and, upon written request, will provide the other Party a Fiscal Report according to Paragraph 4.3, which delineates all payments made and all obligated expenses, along with the Final Research Report described in Paragraph 4.2.

5.4 **Capital Equipment.** Collaborator’s commitment, if any, to provide ICD with capital equipment to enable the research and development activities under the Research Plan appears in

Appendix B. If Collaborator transfers to ICD the capital equipment or provides funds for ICD to purchase it, then ICD will own the equipment. If Collaborator loans capital equipment to ICD for use during the CRADA, Collaborator will be responsible for paying all costs and fees associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and ICD will not be liable for any damage to the equipment.

Article 6. Intellectual Property

6.1 **Ownership of CRADA Subject Inventions, CRADA Data, and CRADA Materials.** Subject to the Government license described in Paragraph 7.5, the sharing requirements of Paragraph 8.1 and the regulatory filing requirements of Paragraph 8.2, the producing Party will retain sole ownership of and title to all CRADA Subject Inventions, all copies of CRADA Data, and all CRADA Materials produced solely by its employee(s). The Parties will own jointly all CRADA Subject Inventions invented jointly and all CRADA Materials developed jointly. A PHS contractor's or grantee's rights in data it generates will not be affected by this CRADA.

6.2 **Reporting.** The Parties will promptly report to each other in writing each CRADA Subject Invention reported by their respective personnel, and any Patent Applications filed thereon, resulting from the research and development activities conducted under this CRADA. Each Party will report all CRADA Subject Inventions to the other Party in sufficient detail to determine inventorship, which will be determined in accordance with U.S. patent law. These reports will be treated as Confidential Information in accordance with Article 8. Formal reports will be made by and to the Patenting and Licensing Offices identified on the Contacts Information Page herein.

6.3 **Filing of Patent Applications.** Each Party will make timely decisions regarding the filing of Patent Applications on the CRADA Subject Inventions made solely by its employee(s), and will notify the other Party in advance of filing. Collaborator will have the first opportunity to file a Patent Application on joint CRADA Subject Inventions and will notify PHS of its decision within sixty (60) days of an Invention being reported or at least thirty (30) days before any patent filing deadline, whichever occurs sooner. If Collaborator fails to notify PHS of its decision within that time period or notifies PHS of its decision not to file a Patent Application, then PHS has the right to file a Patent Application on the joint CRADA Subject Invention, Neither Party will be obligated to file a Patent Application. Collaborator will place the following statement in any Patent Application it files on a CRADA Subject Invention: "This invention was created in the performance of a Cooperative Research and Development Agreement with the **[INSERT into Agency's model as appropriate: National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention],** an Agency of the Department of Health and Human Services. The Government of the United States has certain rights in this invention." If either Party files a Patent Application on a joint CRADA Subject Invention, then the filing Party will include a statement within the Patent Application that clearly identifies the Parties and states that the joint CRADA Subject Invention was made under this CRADA.

6.4 **Patent Expenses.** Unless agreed otherwise, the Party filing a Patent Application will pay all preparation and filing expenses, prosecution fees, issuance fees, post issuance fees, patent maintenance fees, annuities, interference expenses, and attorneys' fees for that Patent Application and any resulting Patent(s). If a license to any CRADA Subject Invention is granted

to Collaborator, then Collaborator will be responsible for all expenses and fees, past and future, in connection with the preparation, filing, prosecution, and maintenance of any Patent Applications and Patents claiming exclusively licensed CRADA Subject Inventions and will be responsible for a pro-rated share, divided equally among all licensees, of those expenses and fees for non-exclusively licensed CRADA Subject Inventions. Collaborator may waive its exclusive option rights at any time, and incur no subsequent financial obligation for those Patent Application(s) or Patent(s).

6.5 **Prosecution of Patent Applications.** The Party filing a Patent Application will provide the non-filing Party with a copy of any official communication relating to prosecution of the Patent Application within thirty (30) days of transmission of the communication. Each Party will also provide the other Party with the power to inspect and make copies of all documents retained in the applicable Patent Application or Patent file. The Parties agree to consult with each other regarding the prosecution of Patent Applications directed to joint CRADA Subject Inventions. If Collaborator elects to file and prosecute Patent Applications on joint CRADA Subject Inventions, then Collaborator agrees to use the U.S.P.T.O. Customer Number Practice and/or grant PHS a power(s) of attorney (or equivalent) necessary to assure PHS access to its intellectual property rights in these Patent Applications. PHS and Collaborator will cooperate with each other to obtain necessary signatures on Patent Applications, assignments, or other documents.

Article 7. Licensing

7.1 **Background Inventions.** Other than as specifically stated in this Article 7, nothing in this CRADA will be construed to grant any rights in one Party's Background Invention(s) to the other Party, except to the extent necessary for the Parties to conduct the research and development activities described in the Research Plan.

7.2 **Collaborator's License Option to CRADA Subject Inventions.** With respect to Government rights to any CRADA Subject Invention made solely by an ICD employee(s) or made jointly by an ICD employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive or nonexclusive commercialization license. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

7.3 **Exercise of Collaborator's License Option.** To exercise the option of Paragraph 7.2 Collaborator must submit a written notice to the PHS Patenting and Licensing Contact identified on the Contacts Information Page (and provide a copy to the ICD Contact for CRADA Notices) within three (3) months after either (i) Collaborator receives written notice from PHS that the Patent Application has been filed or (ii) the date on which Collaborator files the Patent Application. The written notice exercising this option will include a completed "Application for License to Public Health Service Inventions" and will initiate a negotiation period that expires

nine (9) months after the exercise of the option. If PHS has not responded in writing to the last proposal by Collaborator within this nine (9) month period, the negotiation period will be extended to expire one (1) month after PHS so responds, during which month Collaborator may accept in writing the final license proposal of PHS. In the absence of Collaborator's exercise of the option, or upon election of a nonexclusive license, PHS will be free to license the CRADA Subject Invention to others. These time periods may be extended at the sole discretion of PHS upon good cause shown in writing by Collaborator.

7.4 **Government License in ICD Sole CRADA Subject Inventions and Joint CRADA Subject Inventions.** Pursuant to 15 U.S.C. § 3710a(b)(1)(A), for CRADA Subject Inventions owned solely by ICD or jointly by ICD and Collaborator, and licensed pursuant to the option of Paragraph 7.2, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government. In the exercise of this license, the Government will not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. § 552(b)(4) or which would be considered privileged or confidential if it had been obtained from a non-federal party.

7.5 **Government License in Collaborator Sole CRADA Subject Inventions.** Pursuant to 15 U.S.C. § 3710a(b)(2), for CRADA Subject Inventions made solely by an employee of Collaborator, Collaborator grants to the Government a nonexclusive, nontransferable, irrevocable, paid-up license to practice the CRADA Subject Invention or have the CRADA Subject Invention practiced throughout the world by or on behalf of the Government for research or other Government purposes.

7.6 **Third Party License.** Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants Collaborator an exclusive license to a CRADA Subject Invention made solely by an ICD employee or jointly with a Collaborator employee, the Government will retain the right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or, if Collaborator fails to grant a license, to grant a license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(2).

7.7 **Third-Party Rights In ICD Sole CRADA Subject Inventions.** For a CRADA Subject Invention conceived prior to the Effective Date solely by an ICD employee that is first actually reduced to practice after the Effective Date in the performance of the Research Plan, the option offered to Collaborator in Paragraph 7.2 may be restricted if, prior to the Effective Date, PHS had filed a Patent Application and has either offered or granted a license in the CRADA Subject Invention to a third party. Collaborator nonetheless retains the right to apply for a license to any

such CRADA Subject Invention in accordance with the terms and procedures of 35 U.S.C. § 209 and 37 C.F.R. Part 404.

7.8 **Joint CRADA Subject Inventions Not Exclusively Licensed by Collaborator.** If Collaborator does not acquire an exclusive commercialization license in a joint CRADA Subject Invention in all fields of use then, for those fields of use not exclusively licensed to Collaborator, each Party will have the right to use the joint CRADA Subject Invention and to license its use to others, and each Party will cooperate with the other, as necessary, to fulfill international licensing requirements. The Parties may agree to a joint licensing approach for any remaining fields of use.

Article 8. Rights of Access and Publication

8.1 **Right of Access to CRADA Data and CRADA Materials.** ICD and Collaborator agree to exchange all CRADA Data and to share all CRADA Materials. If the CRADA is terminated, both Parties agree to provide CRADA Materials in quantities needed to complete the Research Plan. Such provision will occur before the termination date of the CRADA or sooner, if required by the Research Plan. If Collaborator possesses any human biological specimens from clinical trials under the CRADA, the specimens must be handled as described in the Protocol or as otherwise directed by ICD before the termination date of the CRADA.

8.2 **Use of CRADA Data and CRADA Materials.** The Parties will be free to utilize CRADA Data and CRADA Materials internally for their own purposes, consistent with their obligations under this CRADA. ICD may share CRADA Data or CRADA Materials with any contractors, grantees, or agents it has engaged to conduct the CRADA research and development activities, provided the obligations of this Article 8.2 are simultaneously conveyed. Collaborator may share CRADA Data or CRADA Materials with any contractors, Affiliates, or agents it has engaged to conduct the CRADA research and development activities, provided the obligations of this Article 8.2 are simultaneously conveyed.

8.2.1 **CRADA Data.**

Collaborator and ICD will use reasonable efforts to keep CRADA Data confidential until published or until corresponding Patent Applications are filed. To the extent permitted by law, each Party will have the right to use any and all CRADA Data in and for any regulatory filing by or on behalf of the Party.

8.2.2 **CRADA Materials.**

Collaborator and ICD will use reasonable efforts to keep descriptions of CRADA Materials confidential until published or until corresponding Patent Applications are filed. Collaborator acknowledges that the basic research mission of PHS includes sharing with third parties for further research those research resources made in whole or in part with NIH funding. Consistent with this mission and the tenets articulated in "Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," December 1999, available at http://ott.od.nih.gov/NewPages/RTguide_final.html, following publication either Party may make available to third parties for further research those CRADA Materials made jointly by both PHS and Collaborator.

Notwithstanding the above, if those joint CRADA Materials are the subject of a pending Patent Application or a Patent, or were created using a patent-pending or patented material or technology, the Parties may agree to restrict distribution or freely distribute them. Either Party may distribute those CRADA Materials made solely by the other Party only upon written consent from that other Party or that other Party's designee.

8.3 **Confidential Information.** Each Party agrees to limit its disclosure of Confidential Information to the amount necessary to carry out the Research Plan, and will place a confidentiality notice on all this information. A Party orally disclosing Confidential Information to the other Party will summarize the disclosure in writing and provide it to the other Party within fifteen (15) days of the disclosure. Each Party receiving Confidential Information agrees to use it only for the purposes described in the Research Plan. Either Party may object to the designation of information as Confidential Information by the other Party.

8.4 **Protection of Confidential Information.** Confidential Information will not be disclosed, copied, reproduced or otherwise made available to any other person or entity without the consent of the owning or providing Party except as required by a court or administrative body of competent jurisdiction, or federal law or regulation. Each Party agrees to use reasonable efforts to maintain the confidentiality of Confidential Information, which will in no instance be less effort than the Party uses to protect its own Confidential Information. Each Party agrees that a Party receiving Confidential Information will not be liable for the disclosure of that portion of the Confidential Information which, after notice to and consultation with the disclosing Party, the receiving Party determines may not be lawfully withheld, provided the disclosing Party has been given a reasonable opportunity to seek a court order to enjoin disclosure.

8.5 **Human Subject Protection.** The research to be conducted under this CRADA involves Human Subjects or human tissues within the meaning of 45 C.F.R. Part 46, and all research to be performed under this CRADA will conform to applicable federal laws and regulations. Additional information is available from the HHS Office for Human Research Protections (http://www.hhs.gov/ohrp/).

8.6 **Duration of Confidentiality Obligation.** The obligation to maintain the confidentiality of Confidential Information will expire at the earlier of the date when the information is no longer Confidential Information as defined in Paragraph 2.4 or three (3) years after the expiration or termination date of this CRADA, except for IPI, for which the obligation to maintain confidentiality will extend indefinitely. Collaborator may request an extension to this term when necessary to protect Confidential Information relating to products not yet commercialized.

8.7 **Publication.** The Parties are encouraged to make publicly available the results of their research and development activities. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about a CRADA Subject Invention, CRADA Data, or CRADA Materials, the other Party will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that Confidential Information is protected. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to file a Patent Application.

8.8 **Clinical Investigators' Research and Development Activities.** Although this CRADA does not grant to Collaborator any rights to Inventions made or Raw Data generated by ICD's contractors or grantees, as they are not parties to this CRADA, ICD agrees that:

8.8.1 Subject to the other provisions of Article 8 of this CRADA, ICD will maintain, to the extent permitted by law, all Clinical Data in ICD's Possession and Control as Confidential Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of Test Article and related CRADA Subject Inventions.

8.8.2 With regard to Collaborator's Confidential Information, ICD will require the Clinical Investigators to agree to confidentiality provisions at least as restrictive as those provided in this CRADA and to Collaborator's use of data in accordance with Paragraph 8.8.1 for obtaining regulatory approval for marketing Test Article.

8.8.3 If Collaborator wants access to Raw Data or any other data in the possession of the Clinical Investigators working with Test Article, Collaborator must first contact the CRADA PI. Collaborator will bear any costs associated with Raw Data provided in formats customized for Collaborator.

8.8.4 Collaborator's right to access Clinical Data in ICD's Possession and Control under Paragraph 8.8 is dependent upon Collaborator's continued development and commercialization of Investigational Agent. If Collaborator fails to continue development or commercialization of Investigational Agent without the transfer of its development efforts to another party within ninety (90) days of discontinuation, ICD has the right to make Clinical Data in ICD's Possession and Control available to a third party.

Article 9. Representations and Warranties

9.1 **Representations of ICD**. ICD hereby represents to Collaborator that:

9.1.1 ICD has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that ICD's official signing this CRADA has authority to do so.

9.1.2 To the best of its knowledge and belief, neither ICD nor any of its personnel involved in this CRADA is presently subject to debarment or suspension by any agency of the Government which would directly affect its performance of the CRADA. Should ICD or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, ICD will notify Collaborator within thirty (30) days of receipt of final notice.

9.2 **Representations and Warranties of Collaborator.** Collaborator hereby represents and warrants to ICD that:

9.2.1 Collaborator has the requisite power and authority to enter into this CRADA and to perform according to its terms, and that Collaborator's official signing this CRADA has authority to do so.

9.2.2 Neither Collaborator nor any of its personnel involved in this CRADA, including Affiliates, agents, and contractors are presently subject to debarment or suspension by any agency of the Government. Should Collaborator or any of its personnel involved in this CRADA be debarred or suspended during the term of this CRADA, Collaborator will notify ICD within thirty (30) days of receipt of final notice.

9.2.3 Subject to Paragraph 12.3, and if and to the extent Collaborator has agreed to provide funding under Appendix B, Collaborator is financially able to satisfy these obligations in a timely manner.

9.2.4 The Test Article provided has been produced in accordance with the FDA's current Good Manufacturing Practice set out in 21 C.F.R. §§ 210-211, and ICH QA7, and meets the specifications cited in the Certificate of Analysis and Investigator's Brochure provided.

Article 10. Expiration and Termination

10.1 **Expiration.** This CRADA will expire on the last date of the term set forth on the Summary Page. In no case will the term of this CRADA extend beyond the term indicated on the Summary Page unless it is extended in writing in accordance with Paragraph 13.6.

10.2 **Termination by Mutual Consent.** ICD and Collaborator may terminate this CRADA at any time by mutual written consent.

10.3 **Unilateral Termination.** Either ICD or Collaborator may unilaterally terminate this CRADA at any time by providing written notice at least sixty (60) days before the desired termination date. ICD may, at its option, retain funds transferred to ICD before unilateral termination by Collaborator for use in completing the Research Plan. If Collaborator terminates this Agreement before the completion of all approved or active Protocol(s), then Collaborator will supply enough Test Article (and Placebo, if applicable) to complete these Protocol(s) unless termination is for safety concerns.

10.4 **Funding for ICD Personnel.** If Collaborator has agreed to provide funding for ICD personnel and this CRADA is mutually or unilaterally terminated by Collaborator before its expiration, then Collaborator agrees that funds for that purpose will be available to ICD for a period of six (6) months after the termination date or until the expiration date of the CRADA, whichever occurs sooner. If there are insufficient funds to cover this expense, Collaborator agrees to pay the difference.

10.5 **New Commitments.** Neither Party will incur new expenses related to this CRADA after expiration, mutual termination, or a notice of a unilateral termination and will, to the extent feasible, cancel all outstanding commitments and contracts by the termination date. Collaborator acknowledges that ICD will have the authority to retain and expend any funds for up to one (1) year subsequent to the expiration or termination date to cover any unpaid costs obligated during the term of the CRADA in undertaking the research and development activities set forth in the Research Plan.

10.6 **Collaborator Failure to Continue Development.** If Collaborator suspends development of the Test Article without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, Collaborator agrees that ICD may continue developing the Test Article. In that event, the following will apply:

10.6.1 Collaborator agrees to transfer to ICD all information necessary to enable ICD to contract for the manufacture of the Test Article and, unless abandoned for reasons relating to safety as determined by the data safety monitoring board, to provide the Test Article (and Placebo, if any) in Collaborator's inventory to ICD.

10.6.2 Further, Collaborator hereby grants to ICD a nonexclusive, irrevocable, world-wide, paid-up license to practice, or have practiced for or on behalf of the Government, any Background Invention that Collaborator may currently have or will obtain on the Test Article, its manufacture, or on any method of using the Test Article for the indication(s) described in the Research Plan, including the right to sublicense to third parties.

Article 11. Disputes

11.1 **Settlement.** Any dispute arising under this CRADA which is not disposed of by agreement of the CRADA Principal Investigators will be submitted jointly to the signatories of this CRADA. If the signatories, or their designees, are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the Assistant Secretary for Health (or his/her designee or successor) will propose a resolution. Nothing in this Paragraph will prevent any Party from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing all available judicial remedies.

11.2 **Continuation of Work.** Pending the resolution of any dispute or claim pursuant to this Article 11, the Parties agree that performance of all obligations will be pursued diligently.

Article 12. Liability

12.1 **NO WARRANTIES.** EXCEPT AS SPECIFICALLY STATED IN ARTICLE 9, THE PARTIES MAKE NO EXPRESS OR IMPLIED WARRANTY AS TO ANY MATTER WHATSOEVER, INCLUDING THE CONDITIONS OF THE RESEARCH OR ANY INVENTION OR MATERIAL, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THIS CRADA, OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY INVENTION OR MATERIAL, OR THAT A TECHNOLOGY UTILIZED BY A PARTY IN THE PERFORMANCE OF THE RESEARCH PLAN DOES NOT INFRINGE ANY THIRD-PARTY PATENT RIGHTS.

12.2 **Indemnification and Liability.** Collaborator agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of the use by Collaborator for any purpose of the CRADA Data, CRADA Materials or CRADA Subject Inventions produced in whole or part by ICD employees under this CRADA, unless due to the negligence or willful misconduct of ICD, its employees, or agents. The Government has no statutory authority to indemnify Collaborator. Each Party otherwise will be

liable for any claims or damages it incurs in connection with this CRADA, except that ICD, as an agency of the Government, assumes liability only to the extent provided under the Federal Tort Claims Act , 28 U.S.C. Chapter 171.

12.3 ***Force Majeure.*** Neither Party will be liable for any unforeseeable event beyond its reasonable control and not caused by its own fault or negligence, which causes the Party to be unable to perform its obligations under this CRADA, and which it has been unable to overcome by the exercise of due diligence. If a *force majeure* event occurs, the Party unable to perform will promptly notify the other Party. It will use its best efforts to resume performance as quickly as possible and will suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

Article 13. Miscellaneous

13.1 **Governing Law.** The construction, validity, performance and effect of this CRADA will be governed by U.S. federal law, as applied by the federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any U.S. federal law or regulation, then the U.S. federal law or regulation will preempt that provision.

13.2 **Compliance with Law.** ICD and Collaborator agree that they will comply with, and advise any contractors, grantees, or agents they have engaged to conduct the CRADA research and development activities to comply with, all applicable Executive Orders, statutes, and HHS regulations relating to research on human subjects (45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56) and relating to the appropriate care and use of laboratory animals (7 U.S.C. §§ 2131 et seq.; 9 C.F.R. Part 1, Subchapter A). ICD and Collaborator will advise any contractors, grantees, or agents they have engaged to conduct clinical trials for this CRADA that they must comply with all applicable federal regulations for the protection of Human Subjects, which may include the Standards for Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 164. Collaborator agrees to ensure that its employees, contractors, and agents who might have access to a “select agent or toxin” (as that term is defined in 42 C.F.R. §§ 73.4-73.5) transferred from ICD is properly licensed to receive the “select agent or toxin.”

13.3 **Waivers.** None of the provisions of this CRADA will be considered waived by any Party unless a waiver is given in writing to the other Party. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, will not be deemed a waiver of any rights of any Party.

13.4 **Headings.** Titles and headings of the articles and paragraphs of this CRADA are for convenient reference only, do not form a part of this CRADA, and will in no way affect its interpretation.

13.5 **Severability.** The illegality or invalidity of any provisions of this CRADA will not impair, affect, or invalidate the other provisions of this CRADA.

13.6 **Amendments.** Minor modifications to the Research Plan may be made by the mutual written consent of the CRADA Principal Investigators. Substantial changes to the CRADA, extensions of the term, or any changes to Appendix C will become effective only upon a written amendment signed by the signatories to this CRADA or by their representatives duly authorized

to execute an amendment. A change will be considered substantial if it directly expands the range of the potential CRADA Subject Inventions, alters the scope or field of any license option governed by Article 7, or requires a significant increase in the contribution of resources by either Party.

13.7 **Assignment.** Neither this CRADA nor any rights or obligations of any Party hereunder will be assigned or otherwise transferred by either Party without the prior written consent of the other Party. This CRADA will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

13.8 **Notices.** All notices pertaining to or required by this CRADA will be in writing, signed by an authorized representative of the notifying Party, and delivered by first class, registered, or certified mail, or by an express/overnight commercial delivery service, prepaid and properly addressed to the other Party at the address designated on the Contacts Information Page, or to any other address designated in writing by the other Party. Notices will be considered timely if received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Notices regarding the exercise of license options will be made pursuant to Paragraph 7.3. Either Party may change its address by notice given to the other Party in the manner set forth above.

13.9 **Independent Contractors.** The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations.

13.10 **Use of Name; Press Releases.** By entering into this CRADA, the Government does not directly or indirectly endorse any product or service that is or will be provided, whether directly or indirectly related to either this CRADA or to any patent or other intellectual-property license or agreement that implements this CRADA by Collaborator, its successors, assignees, or licensees. Collaborator will not in any way state or imply that the Government or any of its organizational units or employees endorses any product or services. Each Party agrees to provide proposed press releases that reference or rely upon the work under this CRADA to the other Party for review and comment at least five (5) business days before publication. Either Party may disclose the Title and Abstract of the CRADA to the public without the approval of the other Party.

13.11 **Reasonable Consent.** Whenever a Party’s consent or permission is required under this CRADA, its consent or permission will not be unreasonably withheld.

13.12 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by ICD, or ICD Materials, or ICD’s Confidential Information to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.13 **Entire Agreement.** This CRADA constitutes the entire agreement between the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.

13.14 **Survivability.** The provisions of Paragraphs 3.3, 3.4, 3.8, 4.2, 4.3, 5.3, 5.4, 6.1-9.2, 10.3-10.6, 11.1, 11.2, 12.1-12.3, 13.1-13.3, 13.7, 13.10 and 13.14 will survive the expiration or early termination of this CRADA.

SIGNATURES BEGIN ON THE NEXT PAGE

SIGNATURE PAGE

ACCEPTED AND AGREED

BY EXECUTING THIS AGREEMENT, EACH PARTY REPRESENTS THAT ALL STATEMENTS MADE HEREIN ARE TRUE, COMPLETE, AND ACCURATE TO THE BEST OF ITS KNOWLEDGE. COLLABORATOR ACKNOWLEDGES THAT IT MAY BE SUBJECT TO CRIMINAL, CIVIL, OR ADMINISTRATIVE PENALTIES FOR KNOWINGLY MAKING A FALSE, FICTITIOUS, OR FRAUDULENT STATEMENT OR CLAIM.

FOR ICD:

Signature _____ Date _____

Typed Name:
Title:

FOR COLLABORATOR:

Signature _____ Date _____

Typed Name:
Title:

CONTACTS INFORMATION PAGE

CRADA Notices

For ICD: For Collaborator:

Patenting and Licensing

For ICD: For Collaborator (if separate from above):

Division Director, Division of Technology
Development and Transfer
NIH Office of Technology Transfer
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804
Tel: 301-496-7057
Fax: 301-402-0220

Delivery of Materials Identified In Appendix B (if any)

For ICD: For Collaborator:

ICD Project Officer for Extramural Investigators

Name:
Branch:
Address:
Telephone:

SUMMARY PAGE

EITHER PARTY MAY, WITHOUT FURTHER CONSULTATION OR PERMISSION, RELEASE THIS SUMMARY PAGE TO THE PUBLIC.

TITLE OF CRADA:

PHS [ICD] Component:
ICD CRADA Principal Investigator:

Collaborator:
Collaborator CRADA Principal Investigator:

Term of CRADA: ( ) years from the Effective Date

ABSTRACT OF THE RESEARCH PLAN:

Appendix C

CTEP Exceptions or Modifications to this CRADA (6/26/06)

Appendix C

Exceptions or Modifications to this CRADA

Additions and deletions within Articles of the extramural clinical trial CRADA appear as underline and strikeout, respectively.

"**Test Article**" means, in accordance with 21 C.F.R. § 50.3(j), any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug, and Cosmetic Act that is intended for administration to humans or animals, including a drug or biologic as identified in the Research Plan and Appendix B, that is used within the scope of the Research Plan. The Test Article may also be referred to as Investigational Agent, Study Material, or Study Product. For this Agreement, Investigational Agent means xxxxxxxxxxxx.

Add the following new sections to the **Article 2. Definitions:**

"**Contract**" means a Funding Agreement that is a research and development mechanism that provides that the contractor perform for the benefit of the Government, with an expectation of completion of the stated research goals and the delivery of a report, data, materials or other product. Generally, Contracts are administered under the Federal Acquisition Regulations (FAR) codified at Title 48 C.F.R., Chapter 1 or the Health Services Acquisition Regulations (HSAR) codified at Title 48 C.F.R., Chapter 3.

"**Cooperative Agreement**" means a Funding Agreement that is a species of a Grant, whereby the funding Federal agency intends to be substantially involved in carrying out the research program.

"**CTA**" means Clinical Trial Agreement.

"**CTEP**" means the Cancer Therapy Evaluation Program, DCTD, NCI, a program within NCI which plans, assesses and coordinates all aspects of clinical trials including extramural clinical research programs, internal resources, treatment methods and effectiveness, and compilation and exchange of data.

"**DTP**" means Developmental Therapeutics Program, DCTD, NCI, the program within the NCI which coordinates preclinical development of agents to be evaluated in DCTD-sponsored clinical trials.

"**DCTD**" means Division of Cancer Treatment and Diagnosis, NCI.

"**FDA**" means U.S. Food and Drug Administration.

"**Funding Agreement**" means a Contract, Grant, or Cooperative Agreement entered into between a Federal agency and another party for the performance of experimental, developmental or research work funded in whole or in part by the Federal Government.

"**Grant**" means a Funding Agreement that is an award of financial assistance which may be provided for support of basic research in a specific field of interest to the funding Federal agency.

"**Multi-Party Data**" means clinical data from clinical studies sponsored by NCI pursuant to CTAs or CRADAs, where such data are collected under protocols involving combinations of investigational agents from more than one CTA or CRADA collaborator.

"**Protocol Review Committee**" (or "**PRC**") means the CTEP/DCTD committee that reviews and approves studies involving NCI investigational agents and/or activities supported by NCI.

3.7 **Investigational New Drug Applications.**

3.7.1 DCTD, NCI, as indicated in the Research Plan, will prepare and submit an IND and all Clinical Investigators participating in DCTD-sponsored clinical trials must have completed registration documents on file (1572 forms) with CTEP.

3.7.2 To support the DCTD IND, Collaborator agrees to provide DCTD background data and information necessary to support the IND. Collaborator further agrees to provide a letter of cross-reference to all pertinent regulatory filings including an IND and/or DMF sponsored by Collaborator. Collaborator's employees will be reasonably available to respond to inquiries from the FDA regarding information and data contained in the Collaborator's IND, DMF, other filings, or other information and data provided to DCTD by the Collaborator pursuant to this Article 3. If DCTD has provided information or data to assist Collaborator in its IND filing, DCTD will provide a letter of cross reference to its IND and respond to inquiries related to information provided by DCTD, as applicable.

3.7.3 If Collaborator supplies Confidential Information to DCTD in support of an IND filed by DCTD, this information will be protected in accordance with the corresponding confidentiality provisions of Article 8.

3.7.4 Collaborator may sponsor its own clinical trials and hold its own IND for studies performed outside the scope of this CRADA. These studies, however, should not adversely affect the ability to accomplish the goal of the Research Plan, for example, by competing for the same study population. All data from those clinical trials are proprietary to Collaborator for purposes of this CRADA.

3.7.5 In the event that Canadian institutions are participating on DCTD-sponsored clinical trials, Collaborator will need to assist in the submission of the regulatory documents to the Canadian Health Products and Food Branch to allow for such participation. This may include a letter of cross-reference to an existing Clinical Trials Application (CTA) or a DMF, including supporting documentation on the production of the Investigational Agent. The forms and procedures for preparing Canadian CTAs are available at http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html.

3.8 **Investigational Agent Information and Supply**. Collaborator agrees to provide DCTD without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of formulated and acceptably labeled, clinical-grade Investigational Agent (and, as required by the Protocol(s), Placebo) to complete the clinical trial(s) agreed to and approved under this CRADA. Collaborator will provide a Certificate of Analysis to DCTD for each lot of the Investigational Agent provided. It is understood that DCTD shall take responsibility for and reasonable steps to maintain appropriate records and assure appropriate supply, handling storage, distribution and usage of these materials in accordance with the terms of this Agreement, the Protocol(s) and any applicable laws and regulations relating thereto.

Collaborator agrees to supply sufficient inventory to ensure adequate and timely supply of Investigational Agent for mutually agreed upon Protocol(s). DCTD will provide updated forecasts of amounts of Investigational Agent anticipated for ongoing and anticipated studies. Collaborator further agrees to provide draft Investigational Agent labels to the NCI Pharmaceutical Management Branch (PMB) for review and agrees to reasonable labeling revisions to comply with DCTD label guidelines. NCI NSC (National Service Center) numbers will be required to be on the label of Investigational Agent for all DCTD-sponsored clinical trials.

Furthermore, Collaborator agrees to provide without charge Investigational Agent or unformulated analytical grade Investigational Agent or metabolites, if available, to DCTD to supply to NCI investigators for the development of mutually agreed upon analytical assays, ancillary correlative studies and pre-clinical studies conducted in conjunction with DCTD-sponsored protocols.

Collaborator agrees to allow Investigational Agent to be distributed to NCI investigators for mutually agreeable preclinical studies designed to enhance the basic understanding and development of Investigational Agent. These will include preclinical studies designed to support clinical trials in pediatric patients; preclinical combination studies to provide data in support of a clinical trial and other pertinent requests. All NCI investigators will sign Material Transfer Agreements (MTAs) that acknowledge the proprietary nature of the Investigational Agent to Collaborator and include intellectual property and publication provisions consistent with those in this Agreement and for clinical trials.

For many investigational agents for which NCI collaborates in development, NCI will undertake non-clinical studies to enhance the understanding of the mechanism of action of the investigational agent and its targets such as, but not limited to, the development of assays to detect target modulation, biomarker studies, and pharmacodynamics in conjunction with the conduct of clinical studies sponsored by DCTD. Collaborator agrees to provide Investigational Agent to DCTD for these non-clinical studies. A general plan for the non-clinical studies of the Investigational Agent will be established by the Steering Committee. Manuscripts and presentations related to non-clinical studies will be handled in accordance with Article 8.7 of this CRADA.

Collaborator agrees to provide to the PMB the Investigator's Brochure (IB) for Investigational Agent and all subsequent revisions/editions. In addition to being filed to the CTEP IND, the IB

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will be on file in the PMB and will be distributed to all investigators participating on a clinical trial using the Investigational Agent. Distribution will be accompanied by a statement about the confidentiality of the document and it is anticipated that distribution will be electronic. All electronic distribution will be done using Adobe Acrobat PDF. Any IB received by the PMB that is not in this format will be converted before distribution. Hard copy IBs should be sent

to IB Coordinator, Pharmaceutical Management Branch, CTEP, DCTD, NCI, 6130 Executive Blvd, Room 7149, Rockville, MD 20852. Electronic versions should be emailed to the IB Coordinator at IBCoordinator@mail.nih.gov.

3.9 **Investigational Agent Delivery and Usage**. Collaborator will ship the Investigational Agent and, if required, Placebo to NCI or its designee in containers marked in accordance with 21 C.F.R. § 312.6. NCI agrees that the Clinical Investigators will keep appropriate records and take reasonable steps to ensure that the Investigational Agent is used in accordance with the Protocol(s) and applicable FDA regulations. In addition, NCI agrees that the Investigational Agent (and all Confidential Information supplied by Collaborator relating to the Investigational Agent) will be used solely for the conduct of the CRADA research and development activities. Furthermore, NCI agrees that no analysis or modification of the Investigational Agent will be performed without Collaborator's prior written consent. At the completion of the Research Plan, any unused quantity of Investigational Agent will be returned to Collaborator or disposed as directed by Collaborator. The contact person. for NCI will be Mr. Charles Hall, Chief, Pharmaceutical Management Branch (Telephone Number 301-496-5725) and the Collaborator contact will be XXXXXX (Telephone Number XXXXX).

3.10 **Monitoring.**

3.10.1 DCTD, NCI will be primarily responsible for monitoring clinical sites and for assuring the quality of all clinical data, unless otherwise stated in the Research Plan. Monitoring will comply with FDA Good Clinical Practice (International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guidance; 62 Federal Register 25, 691 (1997)).

3.10.2 Subject to the restrictions in Article 8 concerning IPI, and with reasonable advance notice and at reasonable times, DCTD will permit Collaborator or its designee(s) access to clinical site(s) to monitor the conduct of the research, as well as to audit source documents containing Raw Data, to the extent necessary to verify compliance with FDA Good Clinical Practice and the Protocol(s).

3.11 **FDA Meetings/Communications**. All formal meetings with the FDA concerning any clinical trial within the scope of the Research Plan will be discussed by Collaborator and ICD in advance. Each Party reserves the right to take part in setting the agenda for, to attend, and to participate in these meetings. The Sponsor will provide the other Party with copies of FDA

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meeting minutes, all transmittal letters for IND submissions, IND safety reports, formal questions and responses that have been submitted to the FDA, Annual Reports, and official FDA correspondence, pertaining either to the INDs under this CRADA or to the Clinical Investigators on Protocols performed in accordance with the Research Plan, except to the extent that those documents contain the proprietary information of a third party or dissemination is prohibited by law.

Add a new **Article 3.12** as follows:

3.12 **Steering Committee and CRADA Research**. The Parties agree to establish a Steering Committee comprising at least the CRADA Principal Investigators to conduct and monitor the research of the Investigational Agent in accordance with the CRADA Research Plan. Members of the Steering Committee shall continue to remain employed by their respective employers under their respective terms of employment.

Investigational Agent's development under the CRADA Research Plan shall be a collaborative undertaking by Collaborator and NCI. Details of this development beyond those set forth in the CRADA Research Plan shall be formulated and/or discussed in Steering Committee meeting(s) before implementation of large-scale or resource intensive studies. The clinical development plans formulated by the Steering Committee shall be implemented either intramurally at the NCI or extramurally under NCI-sponsored Funding Agreements.

Additional CRADA information, including Steering Committee meeting reports, Protocol Review Committee records, clinical trial protocols, Institutional Review Board approval information, IND and general regulatory information, and preclinical and clinical data in NCI's possession and control shall remain on file with NCI.

Add a new **Article 3.13** as follows:

3.13 **Clinical Protocols.** Clinical protocol Letters of Intent (LOI) or concepts for each study within the scope of the CRADA Research Plan will be solicited by CTEP from selected intramural and extramural Clinical Investigators. Clinical protocols from each DCTD- and Collaborator-approved LOI or concept will describe in detail the research to be conducted at each center and must be submitted to the Protocol Review Committee (PRC) for review and approval prior to implementation. Each clinical protocol received by NCI will be forwarded electronically to Collaborator for review and comment approximately two weeks before it is reviewed by the PRC. Comments from Collaborator received by CTEP before the PRC meeting will be discussed by the PRC, will be given due consideration, and will be incorporated into the protocol, absent good cause. Comments from either Collaborator or the CTEP staff that are agreed upon in the PRC meeting will be formatted as a consensus review, which is returned to the Clinical Investigator for necessary and/or suggested changes before the protocol can be given final approval and submitted to the FDA. A copy of the final approved protocol will be forwarded to Collaborator within 24 to 48 hours of its submission to the FDA.

4.2 **Final Research and Development Reports.** The Parties will exchange final reports of their results within six (6) months after the expiration or termination of this CRADA. These reports will set forth the technical progress made; any publications arising from the research; and

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the existence of invention disclosures of potential CRADA Subject Inventions and/or any corresponding Patent Applications. Abstracts and publications provided to CTEP by investigators and further provided by CTEP to Collaborator will fulfill this final report obligation.

4.4 **Safety Reports.** DCTD shall report all serious and/or unexpected Adverse Events to FDA in accordance with the reporting obligations of 21 CFR 312.32 and will, within 24 to 48 hours of notification to FDA, forward all such reports to Collaborator. All other Adverse Event reports received by DCTD shall be reported to the FDA consistent with 21 CFR 312.32 and 312.33. In the event that Collaborator informs the FDA of any serious and/or unexpected Adverse Events, Collaborator must notify the NCI at the same time by sending the reports to CTEPSupportAE@tech-res.com. NCI will then notify the Clinical Investigator(s) conducting studies under DCTD-sponsored protocols, if appropriate.

4.5 **Annual Reports.** DCTD will provide Collaborator a copy of the Annual Report concurrently with the submission of the Annual Report to the FDA. Annual Reports will be kept confidential in accordance with Article 8. Collaborator will provide DCTD with a copy of its Annual Report to the FDA if Collaborator is sponsoring studies of Investigational Agent under its own IND.

7.2 **Collaborator's License Option to CRADA Subject Inventions.** With respect to Government rights to any CRADA Subject Invention made solely by an ICD employee(s) or made jointly by an ICD employee(s) and a Collaborator employee(s) for which a Patent Application was filed, PHS hereby grants to Collaborator an exclusive option to elect an exclusive, or co-exclusive, if applicable, or nonexclusive commercialization license. The option to elect a co-exclusive license shall apply when a CRADA Subject Invention is also a CRADA Subject Invention under another CRADA resulting from mutually agreed upon studies as described in Article 8.9 and the field of use of this co-exclusive license shall be to the use of the combination of the Investigational Agent with another agent(s) commensurate with the scope of the Research Plan. The license will be substantially in the form of the appropriate model PHS license agreement and will fairly reflect the nature of the CRADA Subject Invention, the relative contributions of the Parties to the CRADA Subject Invention and the CRADA, a plan for the development and marketing of the CRADA Subject Invention, the risks incurred by Collaborator, and the costs of subsequent research and development needed to bring the CRADA Subject Invention to the marketplace. The field of use of the license will not exceed the scope of the Research Plan.

7.6 **Third Party License.** Pursuant to 15 U.S.C. § 3710a(b)(1)(B), if PHS grants Collaborator an exclusive, or co-exclusive, license to a CRADA Subject Invention made solely by an ICD employee or jointly with a Collaborator employee, the Government will retain the

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right to require Collaborator to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the CRADA Subject Invention in Collaborator's licensed field of use on terms that are reasonable under the circumstances; or, if Collaborator fails to grant a license, to grant a license itself. The exercise of these rights by the Government will only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Collaborator, (ii) the action is necessary to meet requirements for public use specified by federal regulations, and such requirements are not reasonably satisfied by Collaborator; or (iii) Collaborator has failed to comply with an agreement containing provisions described in 15 U.S.C. § 3710a(c)(4)(B). The determination made by the Government under this Paragraph is subject to administrative appeal and judicial review under 35 U.S.C. § 203(2).

8.7 **Publication.** The Parties are encouraged to make publicly available the results of their research and development activities. Before Collaborator or NCI submits a paper or abstract for publication about a CRADA Subject Invention, CRADA Data, or CRADA Materials, the other Party will have thirty (30) days to review proposed manuscripts and three (3) days to review proposed abstracts to assure that Confidential Information is protected. Either Party may request in writing that a proposed publication be delayed for up to thirty (30) additional days as necessary to file a Patent Application. Manuscripts to be submitted for publication by NCI investigators will be sent to NCI's Regulatory Affairs Branch [anshers@mail.nih.gov] for forwarding to Collaborator for review as soon as they are received and in compliance with the timelines outlined above. Abstracts to be presented by NCI investigators will be sent to NCI's Regulatory Affairs Branch [anshers@mail.nih.gov] for forwarding to Collaborator as soon as they are received, preferably no less than three days prior to submission, but prior to presentation or publication, to allow for preservation of U.S. or foreign patent rights.

8.8 **Clinical Investigators' Research and Development Activities.** In pursuing the development of Investigational Agent pursuant to this CRADA, NCI may utilize contractors and extramural investigators that are not NCI employees for part or all of the completion of this Research Plan, which may cover pre-clinical, non-clinical and clinical studies, through Funding Agreements. Participation in DCTD-sponsored clinical trials by these investigators shall be determined after competitive solicitation and review of Protocol Letters of Intent (LOIs) and study protocols by CTEP, NCI. All Funding Agreements for the conduct of extramural clinical trials will include the Intellectual Property Option to Collaborator Terms of Award Addition offering Collaborator first rights of negotiation to extramural inventions (web site: http://ctep.cancer.gov/industry). Although this CRADA does not grant to Collaborator any rights to Inventions made or Raw Data generated by NCI's contractors or grantees, as they are not parties to this CRADA, NCI agrees that:

8.8.1 Subject to the other provisions of Article 8 of this CRADA, NCI will maintain, to the extent permitted by law, all Clinical Data in NCI's Possession and Control as Confidential Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of Investigational Agent and related CRADA Subject Inventions. Similarly, NCI will also maintain, to the extent permitted by law, all data generated in preclinical and non-clinical studies that are in NCI's possession and control as Confidential

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Information, and make them available to Collaborator for its own use and for exclusive use in obtaining regulatory approval for the commercial marketing of Investigational Agent and related CRADA Subject Inventions. Collaborator will not publish any such data provided under the CRADA without NCI's permission. Accordingly, said data shall not be transferable by Collaborator to any third party, except to Collaborator affiliates and development partners, without the written permission of the NCI. Following NCI's permission, the third party shall enter into a Confidential Disclosure Agreement with the NCI and Collaborator, if requested by NCI, before any data can be transferred.

8.8.2 With regard to Collaborator's Confidential Information, NCI will require the Clinical Investigators to agree to confidentiality provisions at least as restrictive as those provided in this CRADA and to Collaborator's use of data in accordance with Paragraph 8.8.1 for obtaining regulatory approval for marketing Investigational Agent.

8.8.3 If Collaborator wants access to Raw Data or any other data in the possession of the Clinical Investigators working with Investigational Agent under a Funding Agreement or other agreements, Collaborator must first contact the Regulatory Affairs Branch (RAB), CTEP, NCI [Telephone 301-496-7912; anshers@mail.nih.gov]. Subsequent to authorization by RAB, Collaborator may directly contact the Clinical Investigators. Collaborator will bear any costs associated with Raw Data provided in formats customized for Collaborator, which costs will be paid by Collaborator directly to the Clinical Investigators.

8.8.4 Collaborator's right to access Clinical Data in NCI's Possession and Control under Paragraph 8.8 is dependent upon Collaborator's continued development and commercialization of Investigational Agent, If Collaborator fails to continue development or commercialization of Investigational Agent without the transfer of its development efforts to another party within ninety (90) days of discontinuation, NCI has the right to make Clinical Data in NCI's Possession and Control available to a third party.

Add a new **Article 8.9** as follows:

8.9 **Multi-Party Data Rights.** For clinical protocol(s) where Investigational Agent is used in combination with another investigational agent supplied to NCI pursuant to a CTA or CRADA between NCI and an entity not a Party to this CRADA [hereinafter referred to as "Third Party"], the access and use of Multi-Party Data by the Collaborator and Third Party shall be co-exclusive as follows:

8.9.1 NCI will provide both Collaborator and Third Party with notice regarding the existence and nature of the agreements governing their collaborations with NIH, the design of the proposed combination protocol(s), and the existence of any obligations that might restrict NCI's participation in the proposed Combination protocols.

8.9.2 Collaborator shall agree to permit use of the Multi-Party Data from these trials by Third Party to the extent necessary to allow Third Party to develop, obtain regulatory approval for, or commercialize its own investigational agent(s). However, this provision

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will not apply unless Third Party also agrees to Collaborator's reciprocal use of Multi-Party Data.

8.9.3 Collaborator and Third Party must agree in writing prior to the commencement of the combination trial(s) that each will use the Multi-Party Data solely for the development, regulatory approval, and commercialization of its own investigational agent(s).

Add a new **Article 8.10** as follows:

8.10 **Access, review and receipt of Identifiable Private Information.** Collaborator access to and review of Identifiable Private Information shall be only for on-site quality auditing. Collaborator will receive Identifiable Private Information only if necessary for purposes of satisfying FDA or other health authorities' reporting requirements, and for internal research purposes, directly related to obtaining regulatory approval of Investigational Agent. Collaborator is prohibited from access, review, receipt, or use of such information for other purposes. All IRB approved protocols and informed consent documents related to this research project will clearly describe this practice. If the Collaborator will have access to Identifiable Private Information, the protocol and the informed consent must clearly state (i) the existence of the Collaborator; (ii) the Collaborator's access to Identifiable Private Information, if any; and (iii) the extent to which confidentiality will be maintained. For clinical protocol(s) involving a third party, the other party's access, review, receipt, or use of Identifiable Private Information shall be subject to the same limitations as described in this Article 8.10.

10.6 **Collaborator Failure to Continue Development.** If Collaborator suspends development of the Investigational Agent without the transfer of its active development efforts, assets, and obligations to a third party within ninety (90) days of discontinuation, Collaborator agrees that ICD may continue developing the Investigational Agent. In that event, the following will apply:

10.6.1 Collaborator agrees to transfer to ICD all information necessary to enable ICD to contract for the manufacture of the Investigational Agent and, unless abandoned for reasons relating to safety as determined by the data safety monitoring board, to provide the Investigational Agent (and Placebo, if any) in Collaborator's inventory to ICD or arrange for an independent contractor to manufacture and provide Investigational Agent to NCI for two years or until the completion of ongoing mutually agreed to studies.

10.6.2 Further, Collaborator hereby grants to ICD a nonexclusive, irrevocable, world-wide, paid-up license to practice, or have practiced for or on behalf of the Government, any Background Invention that Collaborator may currently have or will obtain on the Investigational Agent, its manufacture, or on any method of using the Investigational Agent for the indication(s) described in the Research Plan, including the right to sublicense to third parties.

13.9 **Independent Contractors.** The relationship of the Parties to this CRADA is that of independent contractors and not agents of each other or joint venturers or partners. Each Party will maintain sole and exclusive control over its personnel and operations. If Collaborator elects to perform any portion of the Research Plan through a contractor or consultant, Collaborator agrees to incorporate into such contract all provisions necessary to ensure that the work of such contractor or consultants is governed by the terms of the CRADA, including, but not limited to a provision for the assignment of inventions of the contractor or consultant to the Collaborator.

13.12 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations, including 21 U.S.C. 382 and 21 CFR Part 312.110. If Collaborator has a need to transfer any CRADA Materials made in whole or in part by ICD, or ICD Materials, or ICD's Confidential Information to a person located in a country other than the United States, to an Affiliate organized under the laws of a country other than the United States, or to an employee of Collaborator in the United States who is not a citizen or permanent resident of the United States, Collaborator will acquire any and all necessary export licenses and other appropriate authorizations.

13.14 **Survivability**. The provisions of Paragraphs [3.3, 3.4, 3.8, 4.2, 4.3, 4.4, 5.3, 5.4, 6.1-9.2, 10.3-10.6, 11.1, 11.2, 12.1-12.3, 13.1-13.3, 13.7, 13.10 and 13.14] will survive the expiration or early termination of this CRADA.

Exhibit 10.39

AMENDMENT #1

To Letter of Intent for Proposed CRADA #2166

"Pre-Clinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent"

The purpose of this amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Pre-Clinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other copy is to remain with the Collaborator.

1. Upon final signature, the term of this CRADA Letter of Intent is extended for six months from November 23, 2007 to May 23, 2008.

2. Dr. Lee Jia is removed as an NCI Principal Investigator. The NCI Principal Investigators are Dr. Sherry Ansher and Dr. Howard Streicher.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/Anna D. Barker	01/08/08
Anna D. Barker, Ph.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/Charles Link	1/17/08
	Date

Exhibit 10.40

AMENDMENT #2

To Letter of Intent for Proposed CRADA #2166

"Pre-Clinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent"

The purpose of this amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Pre-Clinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other copy is to remain with the Collaborator.

1. Upon final signature, the term of this CRADA Letter of Intent is extended for six months from May 23, 2008 to November 23, 2008.

2. Drs. Jeffrey Abrams and James Zwiebel are added as NCI Principal Investigators. The NCI Principal Investigators are Dr. Jeffrey Abrams, Dr. Sherry Ansher, Dr. James Zwiebel and Dr. Howard Streicher.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/Anna D. Barker	06/24/08
Anna D. Barker, Ph.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/Nicholas Vahanian	7/7/2008
	Date

Exhibit 10.41

AMENDMENT #3

To Letter of Intent for Proposed CRADA #2166

"Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent"

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from November 23, 2008 to May 23, 2009.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/Anna D. Barker	03/16/09
Anna D. Barker, Ph.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/Nicholas Vahanian	03/24/09
Name: Nicholas Vahanian Title: COO	Date

Exhibit 10.42

AMENDMENT #4

To Letter of Intent for Proposed CRADA #2166

"Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent"

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from May 23, 2009 to November 23, 2009.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/Anna D. Barker	10/16/09
Anna D. Barker, Ph.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/Nicholas Vahanian	10/28/09
Nicholas Vahanian Chief Operating Officer	Date

Exhibit 10.43

AMENDMENT #5

To Letter of Intent for Proposed CRADA #2166

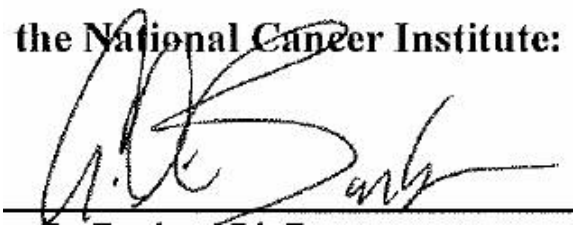
"Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent"

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from November 23, 2009 to May 23, 2010.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:



/s/ — 11/04/09

Anna D. Barker, Ph.D.
Deputy Director, NCI

Date

For NewLink Genetics Corporation:

/s/ — 12/2/09

Nicholas Vahanian, M.D.
Chief Operating Officer

Date

Exhibit 10.44

AMENDMENT #6

To Letter of Intent for Proposed CRADA #2166

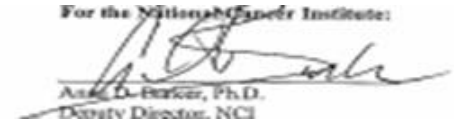
"Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent"

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from May 23, 2010 to November 23, 2010.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:



/s/ — 6/29/10

Anna D. Barker, Ph.D.
Deputy Director, NCI

Date

For NewLink Genetics Corporation:

/s/ — 6/29/10

Nicholas Vahanian, M.D.
Chief Operating Officer

Date

Exhibit 10.45

AMENDMENT #7

To Letter of Intent for Proposed CRADA #2166

"Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent"

The purpose of this Amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl [d]-Tryptophan as an Anticancer Agent." These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this Amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other original is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is extended for six months from November 23, 2010 to, May 23, 2011.

ACCEPTED AND AGREED TO:

For the National Cancer Institute:

/s/ Douglas R. Lowy	11/26/10
Douglas R. Lowy, M.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/ Nicholas Vahanian	1/12/10
Nicholas Vahanian, M.D. Chief Operating Officer	Date

Exhibit 10.46

THIS LICENSE AGREEMENT is made and entered into as of this 13 day of September, 2005, by and between the MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE, INC., a nonprofit Georgia corporation with offices located in the Medical College of Georgia, 1462 Laney Walker Blvd, Room CA-2125, Augusta, Georgia 30912-4810 (hereinafter referred to as "MCGRI") and NEWLINK GENETICS CORPORATION, a Delaware corporation with corporate headquarters located at 2901 South Loop Drive Suite 3900, Ames, Iowa 50010 (hereinafter referred to as "LICENSEE").

WITNESSETH

WHEREAS, the Medical College of Georgia Research Institute (MCGRI) is the assignee of all right, title, and interest in inventions developed by employees of The Medical College of Georgia (MCG) and is responsible for the protection and commercial development of such inventions; and

WHEREAS, David Munn, Andrew Mellor and Stephen Peiper, during the course of his/her/their employment by the Medical College of Georgia (MCG), developed certain inventions **[*]** as more fully defined in Exhibit A; and

WHEREAS, MCGRI wants to have the inventions further developed and made available in commerce for use by the public; and

WHEREAS, LICENSEE represents that it has the necessary expertise and resources to fully develop and commercialize the inventions; and

WHEREAS, LICENSEE wishes to obtain certain rights to pursue the development and commercialization of the inventions; and

WHEREAS, MCGRI wishes to grant LICENSEE such rights in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, for and in consideration of the mutual covenants and the premises herein contained, the parties, intending to be legally bound, hereby agree as follows.

ARTICLE 1. DEFINITIONS

The following terms as used herein shall have the following meaning:

1.1 "Affiliate" shall mean, with respect to Licensee, a person, corporation or other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Licensee. For the purposes of this definition, "control" means the direct or indirect ownership of at least twenty percent (20%) of the outstanding voting securities of the controlled entity.

1.2 "Agreement" or "License Agreement" shall mean this Agreement, including all Exhibits attached to this Agreement.

1.3 "Field of Use" means any and all medical applications, including without limitation, prevention, diagnostics, and therapy, including action as an adjuvant.

1.4 "Improvement" shall mean any invention, that is conceived or reduced to practice in the laboratory of any Inventor (or of his/their collaborators), that relates to an invention claimed in or covered by the Licensed Patents or which is a modification of the inventions claimed in or covered by the Licensed Patents.

1.5 "Indemnitees" shall mean MCGRI, MCGRI's officers and directors, MCG, MCG's employees, and the Inventors, and their heirs, executors, administrators, and legal representatives.

1.6 "Inventors" shall mean David Munn, Andrew Mellor and/or Stephen Peiper, as applicable with respect to each Licensed Patent.

1.7 "License Agreement Year" shall mean the period from July 1 through June 30 of each year during the term of this Agreement.

1.8 "Licensed Patents" shall mean the patent applications and patents identified in EXHIBIT A hereof and any patent applications controlled by MCGRI that claim Improvements, together with all divisionals, continuations, continuations-in-part (to the extent directed to the subject matter specifically described in such patent applications and patents), reissues, and foreign counterparts of such applications or patents.

1.9 "Licensed Product(s)" shall mean any process, service, or product, the manufacture, use, or sale of which is covered by a Valid Claim or incorporates or uses any Licensed Technology.

1.10 "Licensed Technology" shall mean all information and materials proprietary to MCGRI, including designs, technical information, know how, knowledge, data, specifications, test results and other information relating to the Licensed Patents and disclosed by MCGRI to LICENSEE on the date of this Agreement or during the term hereof on an exclusive, confidential basis and which is not available from another source.

1.11 "Licensed Territory" means worldwide.

1.12 "Net Selling Price" of Licensed Products shall mean the gross revenues received by Licensee or its Affiliate from a purchaser of a Licensed Product that is not a Sublicensee of Licensee or its Affiliate (unless such Sublicensee is the end user of such Licensed Product, in which case the amount received therefore shall be deemed to be the amount that would be billed to a third party end user in an arm's-length transaction) including, if applicable, the value of all properties and services received in consideration of a Sale of Licensed Products, less the following items, as allocable to such Licensed Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances; (ii) credits or allowances additionally granted upon returns, rejections or recalls; (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates. Where a Sale is deemed consummated by a gift, use, or other disposition

of Licensed Products for other than a selling price stated in cash, the term "Net Selling Price" shall mean the average gross selling price billed by LICENSEE in consideration of the Sale of comparable Licensed Products during the three (3) month period immediately preceding such Sale, without reduction of any kind; provided, however, that transfers and use of Licensed Products in clinical trials or for promotional or sampling purposes shall not be considered in determining Net Selling Price.

If the Licensed Products are Sold in combination with one or more other products or services which are not Licensed Products, Net Selling Price for such combination products will be calculated on a country-by-country basis by multiplying actual net selling price of such combination products by the fraction A/(A+B) where A is the average invoice price during the period of the Licensed Product when Sold separately, and B is the average invoice price of any other product(s) or services in the combination when Sold separately by Licensee. If the products or services in the combination that are not Licensed Products are not Sold separately by Licensee, Net Selling Price shall be calculated by multiplying actual net selling price of such combination products by the fraction A/C where A is the average invoice price of the Licensed Product when Sold separately and C is the average invoice price of the combination product. If neither the Licensed Product nor the combination product is Sold separately by Licensee, then Net Selling Price for royalty purposes hereunder for Sales of such combination product shall be determined by multiplying the Net Selling Price (calculated in the manner described above) of such combination product by a fraction, determined by mutual agreement of the parties, that reflects the relative contribution in value that the Licensed Product included in the combination product makes to the total value of such combination product.

1.13 "Sale" or "Sold" shall mean the sale, transfer, exchange, or other disposition of Licensed Products for value to a party other than LICENSEE or its Affiliate. Sales of Licensed Products shall be deemed consummated upon the first to occur of: (a) receipt of payment from the purchaser; or (b) if otherwise transferred, exchanged, or disposed of for consideration other than cash whether by gift or otherwise when such transfer, exchange, gift, or other disposition occurs.

1.14 "MCG" shall mean The Medical College of Georgia.

1.15 "Sublicensee" shall mean a third party to whom Licensee or its Affiliate has granted a sublicense under the Licensed patents to make, use, sell, offer to sell or import Licensed Products, beyond the mere right to purchase Licensed Product from Licensee or its Affiliate.

1.16 "Valid Claim" shall mean a claim included among the issued and unexpired Licensed Patents so long as such claim shall not have been irrevocably abandoned or held invalid in an unappealable decision of a court or other authority of competent jurisdiction.

ARTICLE 2. GRANT OF LICENSE

2.1 License. MCGRI hereby grants LICENSEE and its Affiliates an exclusive right and license under the Licensed Patents and Licensed Technology to make, use, import, offer to sell and sell Licensed Products for the Field of Use in the Licensed Territory during the term of this Agreement.

2.2 Sublicensing. Licensee and its Affiliates may sublicense to one or more third parties the rights granted under this Agreement, subject to the prior approval of MCGRI, not to be unreasonably withheld or delayed. If this Agreement is terminated for any reason, any sublicenses granted shall remain in full force and effect and be directly enforceable by MCGRI.

2.3 Retained License. MCGRI retains on behalf of itself, MCG, the Inventors and any academic research collaborators, a royalty-free right and license to make and use Licensed Products and to practice Licensed Technology for research and educational purposes only.

2.4 No Implied License. The license and right granted in this Agreement shall not be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology not specifically identified in this Agreement as Licensed Patents or Licensed Technology.

2.5 Government Rights. The Licensed Patents, Licensed Technology, or portions thereof may have been developed with financial or other assistance through grants or contracts funded by the United States government. LICENSEE acknowledges that in accordance with Public Law 96-517 and other statutes, regulations, and Executive Orders as now exist or may be amended or enacted, the United States government has certain rights in the Licensed Patents and Licensed Technology. LICENSEE shall take all action necessary to enable MCGRI to satisfy its obligations under any federal law relating to the Licensed Patents or Licensed Technology.

2.6 Publications. MCGRI shall have the right to publish any information included in the Licensed Patents subject to the provisions of this § 2.5 and Article 9. MCGRI shall provide to Licensee copies of any proposed presentation or publication or abstract disclosing information included in the Licensed Patents prior to the submission of such documents. Proposed publications and abstracts shall be supplied at least thirty (30) days in advance of submission to a journal, editor, or third party. Licensee may request reasonable changes and/or deletions be made in any proposed publication in order to protect the Licensed Patents and Licensee's confidential information. MCGRI (or any of its personnel) will consider such changes but retains the sole right to determine whether such changes or deletions will be made; but MCGRI agrees that it will honor (and will cause its personnel to honor) Licensee's reasonable requests to remove any confidential information of Licensee included in any such public disclosure. MCGRI agrees to delay such proposed public disclosure for up to ninety (90) days and to use commercially reasonable efforts to cooperate in the filing of a U.S. patent application as provided in Article 7 covering such subject matter prior to public disclosure.

ARTICLE 3. DILIGENCE AND COMMERCIALIZATION

3.1 Licensee agrees to invest **[*]** toward the further development of Licensed Products in the field of cancer therapy within eighteen (18) months after the execution date of the Agreement. If Licensee fails to make the required investment, and does not remedy that failure within sixty (60) days after written notice to Licensee, MCGRI, as its sole and exclusive remedy for such failure, may convert Licensee's right and license in the Field of Use for oncology to non-exclusive.

3.2 Licensee agrees to provide to MCGRI an annual report regarding Licensee's (or its Affiliates' or Sublicensees') progress in other areas of Licensed Product development (outside of cancer). MCGRI has the sole right to determine if non-cancer areas are receiving due diligence in product development in accordance with standards common to the industry, taking into account efficacy, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Licensed Products, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the Licensed Product and alternative products and all other relevant factors. If Licensee has not met basic product development milestones, and does not remedy that failure within sixty (60) days after written notice from MCGRI, Licensee's right and license in that area of the Field of Use (specifically, infectious disease or diagnostics) will revert from exclusive to non-exclusive for that specific application.

ARTICLE 4. CONSIDERATION FOR LICENSE

4.1 License Fee. As partial consideration for the license granted to LICENSEE under this Agreement, LICENSEE shall pay MCGRI a license fee of **[*]**. The license fee shall be paid in two equal installments of **[*]**. The first such installment shall be due within sixty (60) days of signing this Agreement, and the second installment shall be due no later than six (6) months after the first payment. Licensee will issue to MCGRI **[*]** shares of Licensee's common stock (such number of shares to be adjusted for any stock dividends, combinations, splits, recapitalizations, and the like occurring after the effective date of the Agreement), subject to execution and delivery by MCGRI of a stock subscription agreement in the form of Exhibit B hereto. In regard to Improvement technologies created after the signing of this Agreement, if LICENSEE elects to include such technologies under this Agreement, there shall be a one-time License Fee of **[*]** per technology, upon payment of which the new technology is considered part of this Agreement.

4.2 Sublicensing Fee. Licensee shall pay MCGRI **[*]** of any fees or payments or remuneration paid to LICENSEE by a Sublicensee in relation to this License and for rights to all or part of the Licensed Patents (other than research funding, equity, loans or patent costs or fee

reimbursements). Such percentage shall decrease **[*]** for each year of the term of this Agreement in which Licensee expends at least **[*]** towards the development of Licensed Products, but not to go below a floor of **[*]**.

4.3 Royalties. As partial consideration for the license granted to LICENSEE under this Agreement, LICENSEE shall pay MCGRI the following royalties based on the Net Selling Price of the applicable Licensed Products Sold by LICENSEE:

[*]

Notwithstanding the foregoing, if Licensee is required to pay a royalty under a patent license from any third party in order to sell a Licensed Product, then Licensee may reduce the royalty otherwise payable to MCGRI on the Net Selling Price of such Licensed Product by **[*]** of the royalty amounts paid to such third party; provided, however, that in no event will the royalty payable to MCGRI hereunder with respect to such Licensed Product **[*]**. Royalties shall be payable on a Licensed Product-by-Licensed Product and country-by-country basis from first commercial sale of a Licensed Product in a country until the expiration of the last to expire valid claim of the Licensed Patents claiming the manufacture, use or sale of such Licensed Product in such country.

4.4 Minimum Royalties. Prior to the first commercial sale of a Licensed Product, Licensee shall pay to MCGRI an annual license fee equal to **[*]** per License Agreement Year, within sixty (60) days following the end of each License Agreement Year. Following the first commercial sale of a Licensed Product, within sixty (60) days after the end of each License Agreement Year during the term of this Agreement thereafter, if earned royalties for such License Agreement Year are less than **[*]**, Licensee will pay to MCGRI a minimum annual royalty equal to the difference (if any) between **[*]** and earned royalties for such year. For any partial year for which a minimum annual royalty is due hereunder, the amount of such minimum annual royalty shall be pro-rated based on a 365-day year.

4.5 Reimbursement for Patent Expenses. LICENSEE shall reimburse MCGRI for all reasonable, documented out-of-pocket fees, costs, and expenses hereafter during the term of this Agreement paid or incurred by MCGRI in filing, prosecuting, and maintaining the Licensed Patents in the Licensed Territory. LICENSEE shall provide such reimbursement for patent expenses within 30 days of receipt of the itemized invoice.

4.6 Milestone Payments to MCGRI.

4.6.1 Within sixty (60) days of the first achievement by any Licensed Product of the following milestone events, Licensee shall pay (or issue) to MCGRI the indicated consideration:

[*]

4.6.1.1 Initiation of **[*] [*]**

4.6.1.2 Completion of **[*] [*]**

For clarity, each milestone payment above shall be due only once for a particular **[*]** regardless of the number of molecules directed towards such **[*]** pursued in a particular disease category.

4.6.1.3 Within sixty (60) days of the achievement by each Licensed Product of the following milestone events, Licensee shall pay to MCGRI the indicated amount:

4.6.1.4 **[*] [*]**

4.6.1.5 **[*] [*]**

For clarity, each milestone payment indicated above shall be due each time the milestone event is achieved by one or more Licensed Products.

ARTICLE 5. REPORTS AND PAYMENTS

5.1 Within sixty (60) days of September 30, December 31, March 31, and June 30 of each year during the term of this Agreement, up to and including September 30, December 31, March 31 and June 30 following the termination or expiration of this Agreement, LICENSEE shall render a written report to MCGRI setting forth for the preceding calendar quarter, the following as may be applicable under the royalty provisions hereof:

(a) the Net Selling Price of all Licensed Products Sold by LICENSEE, and its Affiliates and Sublicensees under this Agreement; and

(b) the amount of royalty payable; and

(c) any other information reasonably necessary to show the basis on which such royalty has been computed; and

(d) the title of the Licensed Patent(s), the Inventor(s), and the five digit MCG code(s) for the Licensed Patent(s); and

(e) in case no payment is due for any calendar quarter hereunder, LICENSEE shall so report.

5.2 Each royalty report shall be accompanied by the payment of all royalties due for the quarter calendar year in question. Any minimum royalty payment due under Article 4 shall accompany the report for the quarter ending on June 30 of the applicable License Agreement Year.

5.3 All royalties shall be paid in United States funds collectible at one hundred percent (100%) of face value in New York, New York, U.S.A. For purposes of computing the royalty payment on

Sales outside the United States, the royalty payment hereunder shall first be determined in the foreign currency of the country in which Licensed Products are Sold and then converted to United States dollars at the spot rate published by the Wall Street Journal (U.S. edition) on the last day of the quarter for which payment is due.

5.4 In high inflation countries where LICENSEE uses accounting treatment under Statement of Financial Accounting Standards No. 52, Paragraph 11, or the successor equivalent Standard, LICENSEE may for each such country at the end of each quarter convert each month's Sales in that quarter to United States dollars by assuming all Sales in that month occurred on the last day of the month, computing the collection date for that month's Sales to United States dollars at the forecasted exchange rate for that computed collection date; differences between the forecasted exchange rate and the actual exchange rate are to be corrected in the first quarter in which known.

5.5 If Licensed Products are Sold in a country in which conditions or legal restrictions exist which prohibit remittance of United States dollars, LICENSEE shall have the right and option to make the royalty payment for such country by depositing the amount thereof in the currency of the country of Sale at LICENSEE's election, to MCGRI's account in a bank designated by MCGRI in such country.

5.6 Interest. Payments required under this Agreement shall, if overdue, bear interest until payment at a per annum rate **[*],** on the due date. The payment of such interest shall not foreclose MCGRI from exercising any other rights it may have because any payment is late.

5.7 All payments and reports due under this Agreement shall be made in person or via the United States mail or private carrier to the following address:

Office of Technology Transfer and Economic Development
Medical College of Georgia
Attn: Associate Vice President of Technology Transfer & Economic Development
CA-2125
Medical College of Georgia
Augusta, Georgia 30912-9824
Facsimile: (706) 721-2917

5.8 All payments should be made payable to: **The Medical College of Georgia Research Institute**.

ARTICLE 6. RECORDS

6.1 Records of Sales. During the term of this Agreement and for a period of three (3) years thereafter, LICENSEE shall keep at its principal place of business true and accurate records of all Sales in accordance with general accepted accounting principles in the respective country where such Sales occur and in such form and manner so that all royalties owed to MCGRI may be readily and accurately determined. LICENSEE shall furnish MCGRI copies of such records upon MCGRI's request, which shall not be made more often than once per License Agreement Year.

6.2 Audit of Records. MCGRI shall have the right, from time to time at reasonable times during normal business hours through an independent certified public accountant, to examine the records of LICENSEE in order to verify the calculation of any royalties payable under this Agreement. Such

examination and verification shall not occur more than once each License Agreement Year and the calendar year immediately following termination of this Agreement. Unless otherwise agreed in writing by LICENSEE, the fees and expenses of performing such examination and verification shall be borne by MCGRI. If such examination reveals an underpayment by LICENSEE of more than five percent (5%) for any quarter examined, LICENSEE shall pay MCGRI the amount of such underpayment plus interest and shall reimburse MCGRI for all expenses of the accountant performing the examination.

ARTICLE 7. PATENT PROSECUTION

7.1 Prosecution and Maintenance of Licensed Patents. The prosecution and maintenance of the Licensed Patents shall be the primary responsibility of MCGRI using counsel reasonably acceptable to LICENSEE. MCGRI shall keep LICENSEE informed as to all developments with respect to Licensed Patents, including by providing LICENSEE, in a timely manner prior to their due date, with copies of all official documents and correspondence relating to the prosecution, maintenance, and validity of the Licensed Patents. LICENSEE shall be afforded reasonable opportunities to advise MCGRI and cooperate with MCGRI in such prosecution and maintenance. LICENSEE shall advise MCGRI in which countries LICENSEE desires patents be filed, and MCGRI will comply with any such requests. MCGRI shall not unreasonably withhold consent to amend any patent application to include any claims related to Licensed Patents and/or Licensed Technology reasonably requested by LICENSEE to protect the Licensed Products

contemplated to be sold under this Agreement. If LICENSEE should fail to timely make reimbursement for patent expenses incurred under this paragraph as required in Article 4.5 of this Agreement, MCGRI shall have no further obligation to prosecute or maintain the Licensed Patents. MCGRI shall not finally abandon prosecution of any patent application without first notifying LICENSEE sixty (60) days prior to any bar date, of MCGRI's intention and reason therefore, and providing LICENSEE with reasonable opportunity to assume responsibility for prosecution, maintenance and associated costs of such Licensed Patents.

LICENSEE, upon ninety (90) days advance written notice to MCGRI, may advise MCGRI that it no longer wishes to pay expenses for filing, prosecuting or maintaining one or more Licensed Patents. MCGRI may, at its option, elect to pay such expenses or permit such Licensed Patents to become abandoned or lapsed. If MCGRI elects to pay such expenses, such patents shall not be subject to any license granted to LICENSEE hereunder.

7.2 Extension of Licensed Patents. LICENSEE may request that MCGRI have the normal term of any Licensed Patent extended or restored under a country's procedure of extending life for time lost in government regulatory approval processes, and the expense of same shall be borne in accordance with the terms of Article 4.5. LICENSEE shall assist MCGRI to take whatever action is necessary to obtain such extension. In the case of such extension, royalties pursuant to Article 4 hereof shall be payable until the end of the extended life of the patent. In the event that LICENSEE does not elect to extend Licensed Patent(s), MCGRI may, at its own expense, effect the extension of such Licensed Patent(s). If MCGRI elects to pay such expenses, such extended Licensed Patents shall not be subject to any license granted to LICENSEE hereunder.

ARTICLE 8. ABATEMENT OF INFRINGEMENT

8.1 Each party shall promptly inform the other party of any suspected infringement of any Licensed Patents. During the term of this Agreement, MCGRI and LICENSEE shall have the right to institute an action for infringement of the Licensed Patents against any such third party in accordance with the following and subject to the rights of any third parties granted licenses to practice the Licensed Patents by MCGRI:

(a) If MCGRI and LICENSEE agree to institute suit jointly, the suit shall be brought in both their names **[*]** and any recovery or settlement **[*].** LICENSEE and MCGRI shall agree upon the manner in which they shall exercise control over such action. MCGRI may, if it so desires, also be represented by separate counsel of its own selection. The fees for which counsel shall be paid by MCGRI;

(b) In the absence of agreement to institute a suit jointly, MCGRI may institute suit, and, at its option, name LICENSEE as a plaintiff. **[*]**of such litigation and shall be entitled to **[*]**; and

(c) In the absence of agreement to institute a suit jointly and if MCGRI notifies LICENSEE that it has decided not to join in or institute a suit, as provided in (a) or (b) above, LICENSEE may institute suit and, at its option, name MCGRI as a plaintiff. **[*]**of such litigation, including defending any counterclaims brought against MCGRI and paying any judgments rendered against MCGRI, and shall be entitled to **[*]**.

8.2 Should either MCGRI or LICENSEE commence a suit under the provisions of this Article and thereafter elect to abandon such suit, the abandoning party shall give timely notice to the other party who may, if it so desires, continue prosecution of such suit, provided that **[*]** shall be as agreed upon between MCGRI and LICENSEE.

ARTICLE 9. CONFIDENTIALITY

9.1 LICENSEE shall not, without the express written consent of MCGRI, for any reason or at any time either during or subsequent to the term of this Agreement disclose any information contained in the Licensed Patents or Licensed Technology or any other information pertaining to the Licensed Patents and Licensed Technology (collectively referred to as "Proprietary Information") to third parties other than Affiliates and LICENSEE's sublicensees. This obligation of nondisclosure shall not extend to information:

(a) which LICENSEE can demonstrate through documentation to have been within LICENSEE's legitimate possession prior to the time of disclosure of such information to LICENSEE by MCGRI, MCG, or the Inventors;

(b) which was in the public domain prior to disclosure by MCGRI, MCG, or the Inventors, as evidenced by documents published prior to such disclosure;

(c) which, after disclosure by MCGRI, MCG, or the Inventors, comes into the public domain through no fault of LICENSEE;

(d) which is disclosed to LICENSEE by a third party having legitimate possession of the information and the unrestricted right to make such disclosure.

(e) which is required by a valid court order or law, in which case each party would notify the other.

9.2 All reports provided to MCGRI pursuant to this Agreement shall be treated as confidential information of Licensee and shall not be disclosed to any third party without the prior written consent of Licensee. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party; provided, however, that disclosures may be made as required by securities or other applicable laws, or to actual or prospective investors or corporate partners, or to a party's accountants, attorneys, and other professional advisors.

9.3 Prior Agreements. The provisions of this Agreement supersede and shall be substituted for any terms of any prior confidentiality agreement between LICENSEE and MCGRI which are not consistent with this Agreement.

ARTICLE 10. MERCHANTABILITY AND EXCLUSION OF WARRANTIES

10.1 LICENSEE possesses the necessary expertise and skill in the technical areas in which the Licensed Products and Licensed Technology are involved to make, and has made, its own evaluation of the capabilities, safety, utility, and commercial application of the Licensed Patents and Licensed Technology. ACCORDINGLY, to the best of MCGRI's knowledge based on reasonable inquiry, MCGRI represents and warrants that: (i) the execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate action on the part of MCGRI; (ii) MCGRI is the sole and exclusive owner of all right, title, and interest in the Licensed Patents; (iii) it has the right to grant the rights and licenses granted herein; (iv) it has not granted any third party any license, right or interest in any of the Licensed Patents that is inconsistent with the rights granted to Licensee herein and will not grant any third party such a right during the term of this Agreement; and (v) there are no threatened or pending actions, suits, investigations, claims, or proceedings in any way relating to the Licensed Patents.

10.2 Except as expressly set forth in Section 10.1, MCGRI MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE LICENSED PATENTS OR LICENSED TECHNOLOGY AND EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ANY OTHER IMPLIED WARRANTIES WITH RESPECT TO THE CAPABILITIES, SAFETY, UTILITY, OR COMMERCIAL APPLICATION OF LICENSED PATENTS OR LICENSED TECHNOLOGY.

ARTICLE 11. DAMAGES, INDEMNIFICATION, AND INSURANCE

11.1 NO LIABILITY. MCGRI shall not be liable to LICENSEE or LICENSEE's customers for special, incidental, indirect, or consequential damages resulting from defects in the design, testing, labeling, manufacture, or other application of Licensed Products manufactured, tested, designed, or Sold pursuant to this Agreement.

11.2 Indemnification. LICENSEE shall defend, indemnify, and hold harmless the Indemnitees from and against any and all loss, liability, expense, or damage (including investigative costs, court costs and attorneys' fees) Indemnitees may suffer, pay, or incur as a result of claims, demands or actions brought by a third party against any of the Indemnitees arising or alleged to arise by reason of or in connection with

[*] caused or contributed to in whole or in part by LICENSEE's **[*],** except, in each case, to the extent such claims, demands or actions result from the **[*]** of any Indemnitee or the **[*]** in this Agreement. LICENSEE's obligations under this Article shall survive the expiration or termination of this Agreement for any reason.

11.3 Insurance. Without limiting LICENSEE's indemnity obligations under the preceding paragraph, LICENSEE shall maintain throughout the term of this Agreement and for ten (10) years thereafter a liability insurance policy which:

(a) insures Indemnitees for all claims, damages, and actions mentioned in Article 10.1 of this Agreement;

(b) includes a contractual endorsement providing coverage for all liability which may be incurred by Indemnitees in connection with this Agreement;

(c) requires the insurance carrier to provide MCGRI with no less than thirty (30) days written notice of any change in the terms or coverage of the policy or its cancellation; and

(d) prior to the initiation of the first clinical trial involving a Licensed Product, provides product liability coverage in an amount no less than two million dollars ($2,000,000) per occurrence for bodily injury and one million dollars ($1,000,000) per occurrence for property damage, subject to a reasonable aggregate amount.

11.4 Notice of Claims. LICENSEE shall promptly notify MCGRI of all claims involving the Indemnitees and will advise MCGRI of the policy amounts that might be needed to defend and pay any such claims.

ARTICLE 12. TERM AND TERMINATION

12.1 Term. Unless sooner terminated as otherwise provided in this Agreement, the term of this Agreement shall commence on the date hereof and shall continue until the date of expiration of the last to expire of the Licensed Patents, including any renewals or extensions thereof.

12.2 Termination. MCGRI shall have the right to terminate this Agreement upon the occurrence of any one or more of the following events:

(a) failure of LICENSEE to make any two payments consecutive required pursuant to this Agreement when due; or

(b) failure of LICENSEE to render reports to MCGRI as required by this Agreement; or

(c) failure of LICENSEE to notify MCGRI of intent to file bankruptcy as set forth in Article 12.3 below;

(d) the insolvency of LICENSEE; or

(e) the institution of any proceeding by LICENSEE under any bankruptcy, insolvency, or moratorium law; or

(f) any assignment by LICENSEE of substantially all of its assets for the benefit of creditors; or

(g) placement of LICENSEE's assets in the hands of a trustee or a receiver unless the receivership or trust is dissolved within thirty (30) days thereafter; or

(h) the breach of any other material term of this Agreement.

12.3 Notice of Bankruptcy. The LICENSEE must inform MCGRI of its intention to file a voluntary petition in bankruptcy or of another's intention to file an involuntary petition in bankruptcy to be received at least thirty (30) days prior to filing such a petition. A party's filing without conforming to this requirement shall be deemed a material, pre-petition incurable breach.

12.4 Exercise. MCGRI may exercise its right of termination by giving LICENSEE, its trustees or receivers or assigns, thirty (30) days prior written notice of MCGRI's election to terminate. Upon the expiration of such period, this Agreement shall automatically terminate unless the LICENSEE has cured the breach. Such notice and termination shall not prejudice MCGRI's right to receive royalties or other sums due hereunder and shall not prejudice any cause of action of claim of MCGRI accrued or to accrue on account of any breach or default by LICENSEE.

12.5 Failure to Enforce. The failure of MCGRI at any time, or for any period of time, to enforce any of the provisions of this Agreement shall not be construed as a waiver of such provisions or as a waiver of the right of MCGRI thereafter to enforce each and every such provision.

12.6 Termination by LICENSEE. LICENSEE shall have the right to terminate this Agreement upon the occurrence the breach of a material term of this Agreement by MCGRI. In addition, LICENSEE may, upon sixty (60) days written notice to MCGRI, terminate this Agreement by doing all of the following: ceasing to make, have made, use, import, sell and offer for sale all Licensed Products; returning any confidential materials provided to Licensee by MCGRI in connection with this Agreement; paying all amounts owed to MCGRI under this Agreement, up to the date of termination.

12.7 Exercise. LICENSEE may exercise its right of termination based upon a material breach of this Agreement by MCGRI by giving MCGRI thirty (30) days prior written notice of LICENSEE's election to terminate. Upon the expiration of such period, this Agreement shall automatically terminate unless MCGRI has cured the breach. Such notice and termination shall not prejudice LICENSEE's right to pursue any other remedies available to LICENSEE at law.

12.8 Effect. In the event this Agreement is terminated for any reason whatsoever, LICENSEE shall return, or at MCGRI's direction destroy, all plans, drawings, papers, notes, writings and other documents, samples, organisms, biological materials and models pertaining to the Licensed Patents and Licensed Technology, retaining no copies, and shall refrain from using or publishing any portion of the Licensed Patents or Licensed Technology as provided in Article 8 of this Agreement. Upon termination of this Agreement, LICENSEE shall cease manufacturing, processing, producing, using, Selling, or distributing Licensed Products; provided, however, that LICENSEE may continue to Sell in the ordinary course of business for a period of one (1) year reasonable quantities of Licensed Products which are fully manufactured and in LICENSEE's normal inventory at the date of termination if (a) all monetary obligations of LICENSEE to MCGRI have been satisfied and (b) royalties on such sales are paid to MCGRI in the amounts and in the manner' provided in this Agreement. The provisions of Articles 9, 10, and 11 of this Agreement shall remain in full force and effect notwithstanding the termination of this Agreement.

ARTICLE 13. ASSIGNMENT

This Agreement is dependent upon the special relationship between the parties and the special knowledge and unique skills of the LICENSEE. Therefore, LICENSEE shall not grant, transfer, convey, or otherwise assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of MCGRI, except that Licensee may assign this Agreement without the prior written consent of MCGRI, to any Affiliate, or in connection with the transfer or sale of all or substantially all of Licensee's business to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise. This Agreement shall be assignable by MCGRI to MCG, or any other nonprofit corporation which promotes the education or research purposes of MCG.

ARTICLE 14. MISCELLANEOUS

14.1 Export Controls. LICENSEE acknowledges that MCGRI is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities and that MCGRI's obligations under this Agreement are contingent upon compliance with applicable United States export laws and regulations. The transfer of technical data and commodities may require a license from the cognizant agency of the United States government or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without the prior approval of certain United States agencies. MCGRI neither represents that an export license shall not be required nor that, if required, such export license shall issue.

14.2 Legal Compliance. LICENSEE shall comply with all laws and regulations applicable to its manufacture, processing, producing, use, Selling, or distributing of Licensed Products.

14.3 Independent Contractor. LICENSEE's relationship to MCGRI shall be that of a licensee only. LICENSEE shall not be the agent of MCGRI and shall have no authority to act for or on behalf of MCGRI in any matter. Persons retained by LICENSEE as employees or agents shall not by reason thereof be deemed to be employees or agents of MCGRI.

14.4 Patent Marking. LICENSEE shall mark Licensed Products Sold in the United States with United States patent numbers. Licensed Products manufactured or Sold in other countries shall be marked in compliance with the intellectual property laws in force in such foreign countries.

14.5 Use of Names. LICENSEE shall obtain the prior written approval of MCGRI, MCG, or the Inventors prior to making use of their names for any commercial purpose.

14.6 Place of Execution. This Agreement and any subsequent modifications or amendments hereto shall be deemed to have been executed in the State of Georgia, U.S.A. This Agreement shall not become effective or binding upon MCGRI until signed on its behalf by its Executive Director in the State of Georgia, U.S.A.

14.7 Governing Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the parties hereunder, shall be construed under and governed by the laws of the State of Georgia and the United States of America. Only courts in the State of Georgia, U.S.A., shall have jurisdiction to hear and decide any controversy or claim between the parties arising under or relating to this Agreement.

14.8 Entire Agreement. This Agreement constitutes the entire agreement between MCGRI and LICENSEE with respect to the subject matter hereof and shall not be modified, amended or terminated except as herein provided or except by another agreement in writing executed by the parties hereto.

14.9 Severability. All rights and restrictions contained herein may be exercised and shall be applicable and binding only to the extent that they do not violate any applicable laws and are intended to be limited to the extent necessary so that they will not render this Agreement illegal, invalid or unenforceable. If any provision or portion of any provision of this Agreement not essential to the commercial purpose of this Agreement shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, it is the intention of the parties that the remaining provisions or portions thereof shall constitute their agreement with respect to the subject matter hereof, and all such remaining provisions or portions thereof shall remain in full force and effect. To the extent legally permissible, any illegal, invalid or unenforceable provision of this Agreement shall be replaced by a valid provision which will implement the commercial purpose of the illegal, invalid or unenforceable provision. In the event that any provision essential to the commercial purpose of this Agreement is held to be illegal, invalid or

unenforceable and cannot be replaced by a valid provision which will implement the commercial purpose of this Agreement, this Agreement and the rights granted herein shall terminate.

14.10 Force Majeure. Any delays in, or failure of, performance of any party to this Agreement shall not constitute default hereunder, or give rise to any claim for damages, if and to the extent caused by occurrences beyond the control of the party affected, including, but not limited to, acts of God, strikes or other work stoppages; civil disturbances, fires, floods, explosions, riots, war, rebellion, sabotage, acts of governmental authority or failure of governmental authority to issue licenses or approvals which may be required.

ARTICLE 15. NOTICES

All notices, statements, and reports required or contemplated herein by one party to the other shall be in writing and shall be deemed to have been given upon delivery in person or upon the expiration of five (5) days after deposit in a lawful mail depository in the country of residence of the party giving the notice, registered or certified airmail postage prepaid, and addressed as follows:

If to MCGRI:

Associate Vice President
Office of Technology Transfer & Economic Development
Medical College of Georgia Research Institute, Inc.
CA-2125
Medical College of Georgia
Augusta, Georgia 30912-9824
Facsimile: (706) 721-2917

With a copy to:

Legal Advisor
Medical College of Georgia Research Institute, Inc.
CJ-3301
Medical College of Georgia
Augusta, Georgia 30912-4810
Facsimile: (706) 721-7603

If to LICENSEE:

NewLink Genetics Corporation
Chief Medical Officer
2901 South Loop Dr, Suite 3900

Ames, IA 50010
Facsimile: (515) 296-5557

Either party hereto may change the address to which notices to such party are to be sent by giving notice to the other party at the address and in the manner provided above. Any notice herein required or permitted to be given may be given, in addition to the manner set forth above, by telex, facsimile or cable, provided that the party giving such notice obtains acknowledgement by telex, facsimile or cable that such notice has been received by the party to be notified. Notice made in this manner shall be deemed to have been given when such acknowledgement has been transmitted.

IN WITNESS WHEREOF, MCGRI and LICENSEE have caused this Agreement to be signed by their duly authorized representatives as of the day and year indicated below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE, INC.	LICENSEE: NEWLINK GENETICS CORPORATION
By: /s/ Betty Aldridge	By: /s/ Nicholas Vahanian
Name: Betty Aldridge	Name: Nicholas Vahanian
Title: Executive Director	Title: Chief Medical and Operations Officer

EXHIBIT A

LICENSED PATENTS

[*]

EXHIBIT B

STOCK SUBSCRIPTION AGREEMENT

STOCK SUBSCRIPTION AGREEMENT

This Stock Subscription Agreement (the "**Agreement**") is made as of the 13 day of September, 2005, by and between NewLink Genetics Corporation, a Delaware corporation (the "**Company**"), and Medical College of Georgia Research Institution, Inc., a nonprofit Georgia corporation ("**Purchaser**").

W I T N E S S E T H:

WHEREAS, pursuant to the terms of the License Agreement, dated this date, between the Company and the Purchaser (the "**License Agreement**"), the Company has agreed to issue and sell to Purchaser, and Purchaser desires to acquire, **[*]** shares of Common Stock (the "**Common Stock**") of the Company.

NOW, THEREFORE, IT IS AGREED between the parties as follows:

1. **Purchase and Sale; Closing.**

(a) For and in consideration of the license granted pursuant to the License Agreement, Purchaser hereby agrees to Purchase from the Company and the Company agrees to issue and sell to Purchaser **[*]** shares of Common Stock (the "**Shares**").

(b) The Company delivers herewith to Purchaser a certificate registered in Purchaser's name representing the number of Shares purchased hereunder. Purchaser and the Company agree that the value of the Shares is **[*]**.

2. Representations and Warranties of the Purchaser.

Purchaser hereby represents and warrants to the Company as follows:

(a) Purchaser is aware that the Shares to be issued to Purchaser by the Company pursuant to this Agreement have not been registered under the Securities Act of 1933, as amended (the "**Act**"), and that the Shares are deemed to constitute "restricted securities" under Rule 144 promulgated under the Act.

(b) Purchaser is obtaining the Shares for Purchaser's own account and Purchaser has no present intention of distributing or selling said Shares except as permitted under the Act and applicable state securities laws. Purchaser does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person with respect to any of the Shares and Purchaser knows of no public solicitation or advertisement of any offer in connection with the Shares. Purchaser represents that Purchaser has full power and authority to enter into this Agreement.

(c) Purchaser is aware that the purchase of the Shares involves a high degree of risk. Purchaser acknowledges that Purchaser is able to fend for itself, can bear the economic risk of such investment, and has sufficient knowledge and experience in business and financial matters that Purchaser is capable of evaluating the Company, its proposed activities and the risks and merits of the investment in the Shares. Purchaser has the ability to accept the high risk and lack of liquidity inherent in this type of investment.

(d) Purchaser understands that the exemption from registration under Rule 144 will not be available for at least two years from the date of receipt of the Shares unless at

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least one year from the date of receipt (i) a public trading market then exists for the Common Stock of the Company, (ii) adequate information concerning the Company is then available to the public, and (iii) other terms and conditions of Rule 144 are complied with; and that any sale of the Shares may be made only in limited amounts in accordance with such terms and conditions and that after ninety days after the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Shares may be resold by persons other than affiliates in reliance on Rule 144 without compliance with paragraphs (c), (d), (e) and (h) thereof, and by affiliates without compliance with paragraph (d) thereof.

(e) Purchaser is familiar with the Company, the nature of its business, its financial prospects and the merits and risks of an investment in the Company, and has the capacity to protect Purchaser's own interests. Purchaser has been provided with the Company's financial statements and executive summary and has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company. Purchaser has also had the opportunity to ask questions of, and receive answers from the Company and its management regarding the terms and conditions of this investment.

(g) Purchaser is an "accredited investor" as defined in Rule 501 under the Act.

3. Restrictive Legends.

All certificates representing the Shares shall have endorsed thereon the following legends:

(a) "THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND THUS MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER APPLICABLE FEDERAL OR STATE SECURITIES LAWS, OR UNLESS THE COMPANY IS FURNISHED WITH AN OPINION OF COUNSEL ACCEPTABLE TO IT THAT AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE."

(b) "THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A RIGHT OF FIRST REFUSAL OPTION IN FAVOR OF THE CORPORATION AND/OR ITS ASSIGNEE(S), AS PROVIDED IN THE BYLAWS OF THE CORPORATION."

(c) Any legend required to be placed thereon by appropriate state Blue Sky officials.

4. Restrictions on Transfer.

(a) Without in any way limiting the foregoing, Purchaser further agrees that Purchaser shall in no event make any disposition of all or any portion of the Shares which Purchaser is being issued unless and until: (i) there is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement; (ii) such disposition is made in accordance with the provisions of the Company's Bylaws, (iii) Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and (iv) if reasonably requested by the Company, such Purchaser shall have furnished the Company with an opinion of counsel, reasonably satisfactory

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to the Company, that such disposition will not require registration of such shares under the Act. It is agreed that the Company will not require opinions of counsel for transactions made pursuant to Rule 144 except in unusual circumstances.

(b) Purchaser hereby agrees that for a period of 180 days following the effective date of the first registration statement of the Company covering Common Stock (or other securities) to be sold on its behalf in an underwritten public offering, Purchaser shall not, to the extent requested by the Company and any underwriter, sell or otherwise transfer or dispose of (other than to donees who agree to be similarly bound) any Common Stock of the Company held by Purchaser at any time during such period except Common Stock included in such registration.

(c) In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Common Stock held by Purchaser (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

(d) The Company shall not be required (i) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Bylaws or (ii) to treat as owner of such Shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Shares shall have been so transferred.

5. Miscellaneous.

(a) The parties agree to execute such further instruments and to take such further action as may reasonably be necessary to carry out the intent of this Agreement.

(b) Unless otherwise provided, any notice or other communications required or permitted under this Agreement shall be given in writing and shall be mailed by United States first class mail, postage prepaid, sent by facsimile or delivered personally by hand or by a nationally recognized courier addressed to the party to be notified at the address or facsimile number indicated for such person on the signature page hereof, or at such other address or such facsimile number as such party may designate by ten (10) days' advance written notice to the other parties hereto. All such notices and other written communications shall be effective on the date of mailing, confirmed facsimile transfer or delivery.

(c) This Agreement shall be governed by the laws of the State of Iowa and interpreted and determined in accordance with the laws of the State of Iowa, as such laws are applied by Iowa courts to contracts made and to be performed entirely in Iowa by residents of that state.

(d) This Agreement shall inure to the benefit of the successors and assigns of the Company and, subject to the restrictions on transfer herein set forth, shall be binding upon Purchaser, his or her heirs, executors, administrators, successors and assigns.

(e) This Agreement constitutes the full and entire understanding and agreement of the parties with respect to the subject matter hereof and no party shall be liable or bound to any other in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein.

(f) The warranties, representations and covenants of the Purchaser contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement and the Closing.

IN WITNESS WHEREOF**,** the parties hereto have executed this Agreement as of the day and year first above written.

NewLink Genetics Corporation

By: /s/ Nicholas N. Vahanian
Title: Chief Medical & Operations Officer
Address: 2901 S. Loop Drive #3900
Ames, IA 50010
Facsimile No.: (515) 296-5557

Purchaser:

Medical College of Georgia Research Institution, Inc.

By: /s/ Betty Aldridge
Title: Executive Director, MCG Research Institute
Address: CA-2125, 1120 15th Street
Augusta, GA 30901
Facsimile No.: 706/721-2917

Exhibit 10.47

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its inhibitors in Immuno-regulation **[*]** dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was signed

and

Inasmuch as the NewLink has reviewed a new Improvement Technology **[*]**, and wishes to exercise its option to incorporate this technology into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case **[*]** is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of **[*]** is received at MCGRI.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE		NEWLINK GENETICS	
By	/s/Betty Aldridge	By:	/s/Nicholas N. Vahanian
Name:	Betty Aldridge	Name:	Nicholas N. Vahanian
Title:	Executive Director	Title:	Chief Medical and Operations Officer
Date:	4/27/06	Date:	4/21/06

Exhibit 10.48

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its inhibitors in Immuno-regulation **[*]** dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was signed

and

Inasmuch as NewLink has reviewed a new Improvement Technology **[*]**, and wishes to exercise its option to incorporate those technologies into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case **[*]** is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of **[*]** is received at MCGRI.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE		NEWLINK GENETICS	
By	/s/Betty Aldridge	By:	/s/Nicholas N. Vahanian
Name:	Betty Aldridge	Name:	Nicholas N. Vahanian
Title:	Executive Director	Title:	Chief Medical and Operations Officer
Date:	4/27/06	Date:	4/21/06

Exhibit 10.49

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its inhibitors in Immuno-regulation **[*]** dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was signed

and

Inasmuch as the NewLink has reviewed a new Improvement Technology **[*]**, and wishes to exercise its option to incorporate this technology into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case **[*]** is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of **[*]** is received at MCGRI. All Payments due to the **[*]** will be coordinated by MCGRI according to the terms stated in **[*]**.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE		NEWLINK GENETICS	
By	/s/Betty Aldridge	By:	/s/Nicholas N. Vahanian
Name:	Betty Aldridge	Name:	Nicholas N. Vahanian
Title:	Executive Director	Title:	Chief Medical and Operations Officer
Date:	2/13/07	Date:	2/6/07

Exhibit 10.66

EXCLUSIVE LICENSE AGREEMENT

between

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

and

BIOPROTECTION SYSTEMS CORPORATION

for

"Recombinant Yellow Fever Virus as a Vaccine Vector" **[*]**

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EXCLUSIVE LICENSE AGREEMENT

for

"Recombinant Yellow Fever Virus as a Vaccine Vector" **[*]**

This license agreement ("Agreement") is made effective this 29th day of July, 2008 ("Effective Date"), by and between The Regents of the University of California, a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200 ("The Regents"), and acting through its Office of Technology Management, University of California San Francisco ("UCSF"), 185 Berry Street, Suite 4603, San Francisco, California 94107, and BioProtection Systems Corporation, a Delaware corporation, having a principal place of business at 2901 South Loop Drive, Suite 3360, Ames, Iowa 50010-8646 ("Licensee").

BACKGROUND

A. Certain inventions, generally characterized as "Recombinant Yellow Fever Virus as a Vaccine Vector" (collectively "Inventions"), were made in the course of research at the University of California, San Francisco, by Drs. Raul Andino and Andres McAllister Moreno and are claimed in Patent Rights as defined below.

B. The development of the Inventions was sponsored by the Department of Health and Human Services and, as a consequence, this license is subject to overriding obligations to the United States Federal Government under 35 U.S.C. §§ 200-212 and applicable regulations, including a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced the Inventions for or on behalf of the United States Government throughout the world.

C. Licensee wishes to obtain certain rights from The Regents for the commercial development of the Inventions, in accordance with the terms and conditions set forth herein and The Regents is willing to grant those rights so that the Inventions may be developed and the benefits enjoyed by the general public.

D. The scope of such rights granted by The Regents is intended to extend to the scope of the patents and patent applications in Patent Rights, but only to the extent that The Regents has proprietary rights in and to the Valid Claims of such Patent Rights.

E. Licensee is a "small business firm" as defined in 15 U.S.C. §632.

F. Both parties recognize and agree that Earned Royalties are due under this Agreement with respect to specific products, services and methods covered by this Agreement and that such royalties will be paid with respect to both pending patent applications and issued patents, in accordance with the terms and conditions set forth herein.

G. Both parties recognize and agree that Earned Royalties due under this Agreement will be based on Licensee's or a Sublicensee's last act covered by the Patent Rights within the control of Licensee or a Sublicensee, regardless of whether Licensee or a Sublicensee

had control over prior acts; the parties intend that Earned Royalties due under this Agreement will be calculated based on the Net Sales of the product or service resulting from the last such act by Licensee and its Sublicensees.

The parties agree as follows:

1 DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or plural, shall have the following meanings:

1.1 "**API**" or "**Active Pharmaceutical Ingredient**" means a therapeutically active biological or chemical compound that (i) requires regulatory approval by the United States Food and Drug Administration ("FDA") before use in humans; (ii) does not function together with the Licensed Product to achieve the same prophylactic or therapeutic purpose through the same mechanism of action, by targeting the same antigen or the same gene or expressed product of a gene; (iii) is claimed or covered by patent rights that do not claim or cover Licensed Product; and (iv) when Sold as a component of a Combination Product, the market price of such Combination Product is higher than the market price for the Licensed Product portion included within such Combination Product, when such Licensed Product is Sold alone. For clarity, the term "Active Pharmaceutical Ingredient" shall not include excipients, buffers or other similar substances that are typically formulated with the therapeutically active ingredient contained in a drug product to form the final drug product for sale and/or pharmaceutical administration.

1.2 "**Affiliate**" of Licensee means any entity which, directly or indirectly, Controls Licensee, is Controlled by Licensee or is under common Control with Licensee. "Control" means: (i) having the actual, present capacity to elect a majority of the directors of such entity; (ii) having the power to direct at least forty percent (40%) of the voting rights entitled to elect directors; or (iii) in any country where the local law will not permit foreign equity participation of a majority, ownership or control, directly or indirectly, of the maximum percentage of such outstanding stock or voting rights permitted by local law.

1.3 "**Attributed Income**" means the total gross proceeds (exclusive of Earned Royalties of Sublicensees, but including, without limitation, any license fees, maintenance fees, or milestone payments), whether consisting of cash or any other forms of consideration and whether any rights other than Patent Rights are granted, which gross proceeds are received by or payable to Licensee or any Affiliate from any Sublicensee in consideration of the grant of a sublicense under the Patent Rights. Notwithstanding the foregoing, Attributed Income shall not include proceeds attributed in such sublicense or such agreement, arrangement or other relationship to bona fide: **[*]** for the applicable Sublicensee under such sublicense or such agreement, arrangement or other relationship on the basis of full-time equivalent ("FTE") efforts of personnel at or below commercially reasonable and standard FTE rates and/or reimbursement of other research costs (such as capital equipment purchase) on any actual cost basis.

For the avoidance of doubt, any gross proceeds meeting the definition set forth above in this Article 1.2 shall be "Attributed Income" irrespective of whether such gross proceeds are received under one or more separate agreements relating to sublicensing of the Patent Rights and irrespective of how such gross proceeds are referred to or characterized by Licensee, or the Sublicensee.

1.4 "**Combination Product**" means a therapeutic Product that when Sold contains as active ingredients both a Licensed Product and one or more Active Pharmaceutical Ingredients (which are not themselves Licensed Products). For clarity, the entire Combination Product is deemed a Licensed Product.

1.5 "**Commercially Reasonable Efforts**" shall mean, with respect to the efforts and resources to be expended by Licensee (or its Affiliates or any Sublicensees) with respect to any objective under this Agreement, reasonable, diligent, good faith efforts to accomplish such objective as such party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the discovery, development or commercialization of any Product, such efforts shall be substantially equivalent to those efforts and resources commonly used by such party for a product owned by it or to which it has exclusive rights, which product is at a similar stage in its development or product life and is of similar market potential taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the product, the likelihood of regulatory approval, the profitability and commercial potential of the product to the applicable party, alternative products and other relevant factors.

1.6 "**Earned Royalty**" means a royalty as defined in Paragraph 9.1.

1.7 "**Field of Use**" means all uses, applications and indications relating to human health, such as diagnostic, prophylactic and therapeutic applications, including without limitation Licensee's and any Sublicensee's internal research and development use as required to develop such applications and all commercial uses relating to human healthcare. All other uses are excluded.

1.8 "**FTE**" is defined in Paragraph 1.2 (Attributed Income).

1.9 "**Joint Venture**" means any separate entity established pursuant to an agreement between a third party and Licensee and/or Sublicensee to constitute a vehicle for a joint venture, in which the separate entity manufactures, uses, purchases, Sells or acquires Licensed Products from Licensee or Sublicensee.

1.10 "**Know-How**" means the Biological Materials, protocols and other unpatented know-how listed or generally described in Appendix A.

1.11 "**Licensed Method**" means any process, art or method the use or practice of which, but for the license granted in this Agreement, would infringe, or contribute to, or induce the infringement of, any Patent Rights in any country were they issued at the time of the infringing activity in that country.

1.12 "**Licensed Product(s)**" means any Product, (which may include, without limitation, a Product for use or used in practicing a Licensed Method and any Product made by practicing a Licensed Method), the manufacture, use, Sale, offer for Sale or import of which, but for the license granted in this Agreement, would infringe, or contribute to, or induce the infringement of, any Patent Rights in any country were they issued at the time of the infringing activity in that country. For the avoidance of doubt, if such Product is a component of a larger unit such as a kit, composition of matter or combination, then such kit, composition of matter or combination is deemed to be the Licensed Product for purposes of this definition.

1.13 "**Net Invoice Price**" means the gross invoice price charged by, and the value of any other consideration (if any) owed to, Licensee and/or any Sublicensee for a Licensed Product Sold to a third party, less (i) an allowance only for those accounts deemed uncollectible by Licensee (or the

Sublicensee, as applicable) after diligent efforts to collect the amount owed, and (ii) the following items, but only to the extent that they actually pertain to the disposition of such Licensed Product, and are included in the gross invoice price charged or other consideration owed:

1.13.1 Allowances or credits or refunds actually granted to customers for rejections, returns and prompt payment and volume or trade discounts off of the gross invoice price;

1.13.2 Freight, transport packing and insurance charges associated with transportation, to the extent identified separately on a bill or invoice;

1.13.3 Taxes, including Deductible Value Added Tax, tariffs or import/export duties based on Sales when included in the gross invoice price, but excluding value-added taxes other than Deductible Value Added Tax or taxes assessed on income derived from Sales. "Deductible Value Added Tax" means only the portion of the value added tax that is actually incurred and is not reimbursable, refundable or creditable under the tax authority of any country;

1.13.4 normal and customary discounts and rebates given off of the gross invoice price as a part of a formulary or similar program that are allowed, paid or credited to customers, third-party payers, healthcare systems, or administrators for a Licensed Product that is included in such program, as permitted by applicable law;

1.13.5 normal and customary chargebacks and retroactive price reductions that are paid or credited to customers, third-party payers, health care systems, or administrators for a Licensed Product, as permitted by applicable law;

1.13.6 Rebates and discounts off of the gross invoice price paid or credited pursuant to applicable law; and

1.13.7 The invoiced, out-of-pocket cost (or cost of manufacture, if manufactured by Licensee, its Affiliate(s) or any Sublicensees) for drug delivery devices or

vaccine delivery devices specifically for use with and included in the Licensed Product.

1.14 "Net Sale" means:

1.14.1 except in the instances described in Paragraphs 1.14.2, 1.14.3 and 1.14.4 of this Paragraph, the Net Invoice Price;

1.14.2 for any Relationship-Influenced Sale of a Licensed Product, Net Sales shall be based on the Net Invoice Price at which the Relationship-Influenced Sale Purchaser re-Sells such Licensed Product;

1.14.3 in those instances where Licensed Product is not Sold, but is otherwise commercially exploited, the Net Sales for such Licensed Product shall be the Net Invoice Price of products of the same or similar kind and quality, Sold in similar quantities, currently being offered for Sale by Licensee, and/or any Sublicensee. Where such products are not currently being offered for Sale by Licensee, and/or any any Sublicensee, the Net Sales for Licensed Product otherwise exploited, for the purpose of computing royalties, shall be the average Net Invoice Price at which products of the same or similar kind and quality, Sold in similar quantities, are then currently being offered for Sale by other manufacturers. Where such products are not currently Sold or offered for Sale by Licensee, and/or any Sublicensee, or others, then the Net Sales shall be Licensee's, and/ or any Sublicensee's cost of manufacture of Licensed Product, determined according to Generally Accepted Accounting Principles ("GAAP"), **[*]**; and

1.14.4 for a Reacquisition Sale or Exploitation, Net Sales shall mean the Net Invoice Price upon the Reacquisition Sale or Exploitation of a Licensed Product.

1.14.5 For a Combination Product, Net Sales for royalty purposes shall be calculated as:

A/(A+B) x [Net Sales, calculated as in 1.14.1-1.14.4 above, without regard to this formula], where:

(i) "A" is the total of Net Sales of each Licensed Product contained within or used in the Combination Product when Sold separately; and

(ii) "B" is the total of net sales of each API contained within or used in the Combination Product when Sold separately;

provided, however, that in no event shall Net Sales for royalty purposes of a Combination Product be less than **[*]** of the Net Sales calculated as above without regard to this formula.

In the event that either the Licensed Product or any of the APIs included in the Combination Product are not Sold separately, the Net Sales shall be calculated as: (C/D) x [Net Sales, calculated as in 1.14.1-1.14.4 above, without regard to this formula], where:

(i) "C" is the relative contribution, to the overall market value of such Combination Product, of the Licensed Product portion included in the Combination Product; and

(ii) "D" is relative contribution, to the overall market value of such Combination Product, of the API portion(s) included in the Combination Product; with C and D to be established by the mutual agreement of the Parties acting reasonably and in good faith based upon the then-current market conditions; and

provided, however, that in no event shall Net Sales for a Combination Product be less than **[*]** of the Net Sales calculated without regard to this formula.

1.15 "**New Developments**" means inventions, or claims to inventions, which constitute advancements, developments or improvements, whether or not patentable and whether or not the subject of any patent application, which are not sufficiently supported by the specification of a previously-filed patent or patent application within the Patent Rights to be entitled to the priority date of the previously-filed patent or patent application.

1.16 "**Patent Prosecution Costs**" is defined in Paragraph 12.4.

1.17 "**Patent Rights**" means to the extent assigned to or otherwise obtained by The Regents, the following United States patents and patent applications and all rights thereunder:

UC Case Number	United States Application Number or United States Patent Number	Filing or Issue Date
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

The term "Patent Rights" shall also mean, to the extent assigned to or otherwise obtained by The Regents, any reissues, extensions, substitutions, continuations, divisions, and continuation-in-part applications (but excluding those Valid Claims in the continuation-in-part applications that are not supported in the specification of and not entitled to the priority date of the parent application). This definition of Patent Rights excludes any rights in and to New Developments.

1.18 "**Product**" means any kit, article of manufacture, composition of matter, material, compound, component or product.

1.19 "**Reacquisition Sale or Exploitation**" means those instances where Licensee, or a Sublicensee, acquires a Licensed Product and then subsequently Sells or otherwise commercially exploits such Licensed Product.

1.20 "**Related Party**" means a corporation, firm or other entity with which, or individual with whom, Licensee, and/or any Sublicensee (or any of its respective stockholders, subsidiaries or Affiliates) have any agreement, understanding or arrangement (for example, but not by way of limitation, an option to purchase stock or other equity

interest, or an arrangement involving a division of revenue, profits, discounts, rebates or allowances) unrelated to the Sale or exploitation of the Licensed Products and due to such other agreement, understanding or arrangement, the amounts, if any, charged by Licensee, or any Sublicensee to such entity or individual for the Licensed Product, is less than Licensee or Sublicensee (as applicable) otherwise would have charged for such Licensed Product.

1.21 "**Relationship-Influenced Sale**" means a Sale of a Licensed Product, or any other commercial exploitation of the Licensed Product or Licensed Method, between Licensee and/or any Sublicensee and (i) an Affiliate; (ii) a Joint Venture; (iii) a Related Party or (iv) Licensee or a Sublicensee.

1.22 "**Relationship-Influenced Sale Purchaser**" means the purchaser of Licensed Product in a Relationship-Influenced Sale.

1.23 "**Sale**" means the act of selling, leasing or otherwise commercially transferring, providing, or furnishing for use for any consideration. Correspondingly, "Sell" means to make or cause to be made a Sale and "Sold" means to have made or caused to be made a Sale.

1.24 "**Sublicensee**" means any person or entity (including any Affiliate or Joint Venture) to which any of the license rights granted to Licensee hereunder are sublicensed.

1.25 "**Sublicense Fee**" is defined in Paragraph 8.1.

1.26 "**Valid Claim**" means a claim of a patent or patent application in any country that (i) has not expired; (ii) has not been disclaimed; (iii) has not been cancelled or superseded, or if cancelled or superseded, has been reinstated; and (iv) has not been revoked, held invalid, or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such claim in such country from which no further appeal has or may be taken.

2 GRANT

2.1 Subject to the limitations and other terms and conditions set forth in this Agreement including the license granted to the United States Government set forth in the Background and in Paragraph 2.4.1, The Regents grants to Licensee a license under its rights in and to Patent Rights to make, use, Sell, offer for Sale and import Licensed Products and to use and practice the Patent Rights and Licensed Methods, in the United States and in other countries where The Regents may lawfully grant such licenses, only in the Field of Use.

2.2 Except as otherwise provided for in this Agreement, the license granted under Patent Rights in Paragraph 2.1 is exclusive,

2.3 Subject to the limitations and other terms and conditions set forth in this Agreement including the license granted to the United States Government set forth in the Background and in Paragraph 2.4.1, The Regents grants to Licensee a non-exclusive

license under its rights in and to Know-How to use solely for the research, development and commercialization of Licensed Products only in the Field of Use.

2.4 The license granted in Paragraphs 2.1 and 2.2 is subject to the following:

2.4.1 The obligations to the United States Government under 35 U.S.C. §§ 200-212 and all applicable governmental implementing regulations, as amended from time to time, including the obligation to report on the utilization of the Inventions as set forth in 37 CFR. § 401.14(h), and all applicable provisions of any license to the United States Government executed by The Regents; and

2.4.2 the National Institutes of Health "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources," 64 F.R. 72090 (Dec. 23, 1999), as amended from time to time.

2.5 The license granted in Paragraphs 2.1, 2.2 and 2.3 is limited to activities, methods and products that are within the Field of Use. For other activities, methods and products outside the Field of Use, Licensee has no license under this Agreement.

2.6 The Regents reserves and retains the right (and the rights granted to Licensee in this Agreement shall be limited accordingly) to make, use and practice the Inventions, and any technology relating to the Inventions and to make and use any Products and to practice any process that is the subject of the Patent Rights (and to grant any of the foregoing rights to other educational and non-profit institutions) for educational and research purposes, including without limitation, any sponsored research performed for or on behalf of commercial entities and including publication and other communication of any research results. For the avoidance of doubt, to the extent the Inventions and any technology relating to it are not the subject of the exclusive license under the Patent Rights granted to the Licensee hereunder, The Regents shall be free to make, use, Sell, offer to Sell, import, practice and otherwise commercialize and exploit (including to transfer, license to, or have exercised by, third parties) for any purpose whatsoever and in its sole discretion, such Inventions, and any Products or processes that are the subject of any of the foregoing.

2.7 Because the Inventions were made under funding provided by the United States Government, Licensed Products, the Inventions, and any products embodying the Inventions sold in the United States will be substantially manufactured in the United States to the extent required by law or regulation. The Regents agree to use reasonable efforts to seek an exemption from the foregoing requirement, if requested by Licensee, based upon reasonable reasons justifying such exemption.

2.8 Promptly after the Effective Date, The Regents will disclose or provide, as appropriate, to Licensee the Know-How in Appendix. A (to the extent not otherwise disclosed within the Patent Rights disclosed to Licensee).

3 SUBLICENSES

3.1 The Regents also grants to Licensee the right to sublicense to third parties (including to Affiliates and Joint Ventures) the rights granted to Licensee hereunder, with no right to further sublicense except as provided below, as long as Licensee has current exclusive rights under this Agreement. Each Sublicensee must be subject to a written sublicense agreement. All sublicenses will be subject to all terms and conditions of this Agreement, will include all of the rights of, and will require the performance of all the obligations due to, The Regents (and, if applicable, the United States Government and other sponsors) to the extent that such obligations are not performed by Licensee, other than those rights and obligations specified in Article 6 (License Issue Fee), Article 7 (License Maintenance Fee) and Paragraph 9.3 (Minimum Annual Royalty) and Paragraphs 21.4 and 21.5 (reimbursement for Patent Prosecution Costs). For the avoidance of doubt, Licensee shall have no right to permit any Sublicensee and no Sublicensee shall have any right to further sublicense any of the rights granted to Licensee hereunder without the prior written consent of The Regents, such consent not to be unreasonably withheld or delayed, except that each Sublicensee (except Affiliates and Joint Ventures) may sublicense to its Affiliates (as affiliate is defined in Paragraph 1.1 with Sublicensee substituted for Licensee in the definition), to the extent needed for the development and commercialization of Licensed Products in accordance with this Agreement. Also, for the avoidance of doubt, Affiliates and Joint Ventures shall have no licenses under this Agreement unless such Affiliates and Joint Ventures are granted a sublicense. For the purposes of this Agreement, any act or omission by a Sublicensee that would be a breach of this Agreement if imputed to Licensee will be deemed to be a breach by Licensee of this Agreement.

3.2 Licensee will notify The Regents of each sublicense granted hereunder and will provide The Regents with a complete copy of each sublicense (along with a summary of the material terms of each such sublicense) and each amendment to such sublicense within thirty (30) days of issuance of such sublicense or such amendment. Licensee will use reasonable efforts to collect from Sublicensees all fees, payments, royalties and the cash equivalent of any consideration due under the applicable sublicense agreements and will pay to The Regents all amounts due The Regents under this Agreement based on all Sublicensee's activities. For clarity, even if Licensee grants a sublicense that contains a provision for payment to Licensee (or its Affiliate) of royalties by any Sublicensee in an amount that is less than the Earned Royalty required to be paid under Paragraph 9.1 below based on the sales of Licensed Product by such Sublicensee, Licensee will pay to The Regents a total amount equal to the Earned Royalty based on the Sublicensees' Net Sales as provided for in Paragraph 9.1. Licensee will require Sublicensees to provide it with copies of all progress reports and royalty reports in accordance with the provisions herein and Licensee will collect and deliver all such reports due The Regents from Sublicensees.

3.3 If Licensee licenses to a third party patent rights assigned to or otherwise acquired by Licensee ("Licensee's Patent Rights"), and it believes, in good faith, that the recipient of such license will infringe Patent Rights in practicing Licensee's Patent Rights, then Licensee will not separately grant a license to such recipient under Licensee's Patent Rights without concurrently granting a sublicense under Patent Rights consistent with Section 3.1 under this Agreement.

3.4 Upon any expiration or termination of this Agreement for any reason, all sublicenses shall automatically terminate, unless The Regents, at its sole discretion, agrees in writing to an assignment to The Regents of any sublicense. In the event of termination of this Agreement and if The Regents accepts assignment of any sublicense, The Regents will not be bound by any grant of rights broader than or will not be required to perform any obligation other than those rights and obligations contained in this Agreement. Moreover, if The Regents accepts assignment of a sublicense in such

case, The Regents will have the sole right to modify each such assigned sublicense to include all of the rights of The Regents (and, if applicable, the United States Government and other sponsors) that are contained in this Agreement, including the payment of Earned Royalties directly to The Regents by the Sublicensee as if it were Licensee at a rate that is no lower than the rate set forth in Article 9 (Earned Royalties and Minimum Annual Royalties) in accordance with Article 5 (Payment Terms).

4 MANDATORY SUBLICENSING

4.1 If The Regents (as represented by the actual knowledge of the licensing professional responsible for administration of this Agreement) becomes aware of, or if a third party becomes aware of and notifies such licensing professional of an application or use for Licensed Products within the licensed Field of Use but for which Licensed Products have not been developed or are not, at such time, being developed by Licensee, then The Regents, through the Office of Technology Management, may give written notice to Licensee thereof.

4.2 Within ninety (90) days of such notice, Licensee shall give The Regents written notice stating whether Licensee (or its Affiliate or Sublicensee) agrees to develop and commercialize Licensed Products for such application ("New Licensed Products"). Such notice shall be accompanied by (i) a reasonably detailed development schedule, including specific diligence requirements and development milestones, for the development of New Licensed Products; and (ii) a reasonably detailed business plan for the development, marketing and commercialization of New Licensed Products (collectively, the "Development Plan"). If Licensee has not notified The Regents, in accordance with the foregoing, that Licensee (or its Affiliate or Sublicensee) agrees to develop and commercialize such New Licensed Products within such ninety (90) day period, or if the Development Plan is not reasonably acceptable to The Regents, then Licensee shall be deemed to not so agree.

4.3 If Licensee has notified The Regents, as set forth in Paragraph 4.2, that it (or its Affiliate or Sublicensee) intends to develop and commercialize such New Licensed Products, then Licensee (or its Affiliate or Sublicensee) shall (i) diligently proceed with the development, manufacture and commercialization of such New Licensed Products in accordance with the Development Plan and (if required regulatory approvals are obtained) earnestly and diligently endeavor to market the same in accordance with the Development Plan and in quantities sufficient to meet market demand; and (ii) Licensee shall submit a written progress report setting forth in detail the status of such development, manufacture and commercialization every six (6) months to The Regents.

4.4 If Licensee does not agree, as set forth in Paragraph 4.2, to develop and commercialize such New Licensed Products, or if Licensee (or its Affiliate or Sublicensee, as applicable) materially fails to diligently pursue the development and commercialization thereof in accordance with the Development Plan and such failure is not cured within 90 days of written notice of such failure, then The Regents shall have the right to seek one or more third parties for the development and commercialization of such New Licensed Products and refer such third party to Licensee so that such third party may request a sublicense allowing for development and commercialization of such New Licensed Products, provided however that Licensee shall not in any event be required to grant to any such third party a sublicense with respect to any Licensed Product then in development or being commercialized by Licensee (or its Affiliate or Sublicensee) for other uses or indications within the licensed Field of Use. If the third party requests a sublicense, then Licensee shall report such request, together with the terms and conditions thereof proposed by such third party, to The Regents within thirty (30) days from the date of such request, and Licensee shall negotiate with such third party reasonably and in good faith and seek to reach agreement on the terms of such a sublicense, which shall be commercially reasonable for Licensee.

4.5 If such a third party has requested a sublicense with respect to New Licensed Products and has proposed commercially reasonable terms, and Licensee does not grant a sublicense to the third party within a reasonable time after such request under commercially reasonable terms, then Licensee shall promptly, or, in the event of such refusal, within thirty (30) days after such refusal, submit to The Regents a written report specifying the license terms proposed by the third party and a written justification for the Licensee's refusal or failure to grant such sublicense. If The Regents, acting reasonably and in good faith, determines that the terms of the sublicense proposed by the third party are commercially reasonable under the circumstances, then The Regents shall have the right to grant to the third party (and the rights granted to Licensee in this Agreement shall be limited accordingly) a license to make, have made, use, sell, offer for sale and import the requested New Licensed Products and to practice the Licensed Methods (within the licensed Field of Use and otherwise) with respect to the specific application covered by the request, at substantially the same terms last proposed to Licensee by the third party providing that the royalty rates are not lower than the earned royalties owed by Licensee hereunder and provided further that The Regents may not in any event grant such third party any license rights with respect to any Licensed Product then in development or being commercialized by Licensee (or its Affiliate or Sublicensee) or with respect to any uses or indications within the licensed Field of Use other than the specific use requested by such third party that is the New Licensed Product.

5 PAYMENT TERMS

5.1 Paragraphs 1.11, 1.12 and 1.17 define Licensed Method, Licensed Product, and Patent Rights, so that Earned Royalties are payable on products and methods covered by Valid Claims in the Patent Rights (which includes both pending patent applications and issued patents). Earned Royalties will accrue for the duration of Patent Rights and will accrue when Licensed Products are invoiced, or if not invoiced, when delivered or otherwise exploited by Licensee or Sublicensee in a manner constituting a Net Sale as defined in

Paragraph 1.14. Sublicense Fees with respect to any Attributed Income shall accrue to The Regents within thirty (30) days of the date that such Attributed Income is received by Licensee. Licensee shall use diligent efforts to collect from its Sublicensees all Attributed Income that is due to Licensee, and if a Sublicensee materially defaults in an obligation to pay Attributed Income, and does not cure such default within ninety (90) days of the date such Attributed Income is due, then Licensee shall terminate the corresponding sublicense.

5.2 Licensee will pay to The Regents all Earned Royalties, Sublicense Fees and other consideration payable to The Regents quarterly on or before February 28 (for the calendar quarter ending December 31), May 31 (for the calendar quarter ending March 31), August 31 (for the calendar quarter ending June 30) and November 30 (for the calendar quarter ending September 30) of each calendar year. Each such payment will be for Earned Royalties, Sublicense Fees and other consideration which has accrued within Licensee's most recently completed calendar quarter.

5.3 All consideration due The Regents will be payable and made in United States dollars by check payable to "The Regents of the University of California" or by wire transfer to an account designated by The Regents. Licensee is responsible for all bank or other transfer charges. When Licensed Products are Sold for monies other than United States dollars, the Earned Royalties and other consideration will first be determined in the foreign currency of the country in which such Licensed Products were Sold and then converted into equivalent United States dollars. The exchange rate will be the average exchange rate quoted in the *The Wall Street Journal* during the last thirty (30) days of the reporting period.

5.4 Sublicense Fees and Earned Royalties on Net Sales of Licensed Products and other consideration accrued in, any country outside the United States may not be reduced by any taxes, fees or other charges imposed by the government of such country, except those taxes, fees and charges allowed under the provisions of Paragraphs 1.13 (Net Invoice Price) and 1.14 (Net Sale) or for withholding taxes required to be assessed by any government upon the payments being made to The Regents.

5.5 Notwithstanding the provisions of Article 28 (Force Majeure) if at any time legal restrictions prevent the prompt remittance of Earned Royalties or other consideration owed to The Regents by Licensee with respect to any country where a sublicense is issued or a Licensed Product is Sold or otherwise exploited, then Licensee shall convert the amount owed to The Regents into United States dollars and will pay The Regents directly from another source of funds in order to remit the entire amount owed to The Regents.

5.6 In the event that any patent or claim thereof included within the Patent Rights is held invalid in a final decision by a court of competent jurisdiction and last resort and from which no further appeal can be taken, then all obligation to pay royalties based on that patent or claim or any claim patentably indistinct therefrom will cease as of the date of final decision. Licensee will not, however, be relieved from paying any royalties that accrued before such final decision and Licensee shall be obligated to pay the full amount

of royalties due hereunder to the extent that The Regents licenses one or more Valid Claims within the Patent Rights to Licensee that cover such Licensed Products.

5.7 To the extent required by law, no Earned Royalties will be collected or paid hereunder to The Regents on Licensed Products Sold to, or otherwise exploited for, the account of the United States Government as provided for in the license to the United States Government. Licensee, and its Sublicensees will reduce the amount charged for Licensed Products Sold to, or otherwise exploited by, the United States Government by an amount equal to the Earned Royalty for such Licensed Products otherwise due The Regents. Such reduction in Earned Royalties will be in addition to any other reductions in price required by the United States Government.

5.8 In the event that royalties, fees, reimbursements for Patent Prosecution Costs or other monies owed to The Regents under this Agreement are not received by The Regents when due, Licensee will pay to The Regents interest on the amount of the late payment at a rate of ten percent (10%) simple interest per annum. Such interest will be calculated from the date payment was due until actually received by The Regents. Such accrual of interest will be in addition to and not in lieu of, enforcement of any other rights of The Regents due to such late payment.

6 LICENSE ISSUE FEE

Licensee will pay to The Regents a license issue fee of **[*]** within seven (7) days of the Effective Date. This fee is non-refundable, non-cancelable and is not an advance or otherwise creditable against any royalties or other payments required to be paid under the terms of this Agreement.

7 LICENSE MAINTENANCE FEE

7.1 Beginning on the one-year anniversary of the Effective Date and continuing annually on each anniversary of the Effective Date (except as otherwise provided in Section 7.2), Licensee will also pay to The Regents a license maintenance fee as follows:

7.1.1 **[*]** until and including the **[*]**;

7.1.2 **[*]** subsequent to the **[***]**.

7.2 The license maintenance fee is not due on any anniversary of the Effective Date if on that date, Licensee (or its Affiliate or Sublicensee) is Selling or otherwise exploiting Licensed Products and is paying an Earned Royalty to The Regents on the Net Sales of such Licensed Products. The license maintenance fee is non-refundable and is not an advance or otherwise creditable against any royalties or other payments required to be paid under the terms of this Agreement.

8 PAYMENTS ON SUBLICENSES

8.1 Licensee will pay to The Regents the following percentages of all Attributed Income ("Sublicense Fees"), according to the stage of development of Licensed Products:

8.1.1 **[*]** under sublicenses executed before **[*]**;

8.1.2 **[*]** under sublicenses executed subsequent to **[*]** but prior to **[*]**;

8.1.3 **[*]** under sublicenses executed subsequent to **[*]** but prior to **[*]**;

8.1.4 **[*]** under sublicenses executed after **[*]**.

Sublicense Fees are non-refundable and non-creditable.

9 EARNED ROYALTIES AND MINIMUM ANNUAL ROYALTIES

9.1 Licensee will pay to The Regents an "**Earned Royalty**" of:

9.1.2 **[*]** of the Net Sales of Licensed Product(s) or Licensed Method **[*]** by Licensee or any Affiliate or Sublicensee; and

9.1.3 **[*]** of the Net Sales of Licensed Product(s) or Licensed Method **[*]** by Licensee or any Affiliate or Sublicensee.

9.2 In the event it becomes necessary for Licensee (or its Affiliate or Sublicensee) to license patent rights owned by an unaffiliated third party in order to make, use, Sell, offer to Sell or import Licensed Product or Licensed Method, and Licensee (or its Affiliate or Sublicensee) is required to pay a royalty to the unaffiliated third party under a separate license agreement in order to practice Licensed Methods, and/or to make, use, Sell, offer to Sell or import Licensed Products, in addition to Licensee paying to The Regents a royalty under this Agreement for such activity, and the combined earned royalty due all the parties exceeds **[*]**, then the Earned Royalty to be paid to The Regents under this Agreement by Licensee shall be reduced on a going-forward basis by an amount equal to **[*]** of the royalty rate due to such unaffiliated third party that is in excess of the **[*]** combined royalty rate due to all parties. However, in no event shall the amount paid to The Regents be reduced below **[*]** of the original Earned Royalty amount due The Regents under Paragraph 9.1 above. No reduction pursuant to this Section 9.2 will be available with respect to a Combination Product if no such royalty would have been payable to such unaffiliated third party if the relevant API were not included in such Combination Product.

9.3 In the event it becomes necessary for the Licensee or its Affiliate or a Sublicensee to license patent rights owned by an unaffiliated third party in order to make, use, Sell, offer to Sell or import the Licensed Product component of a Combination Product, and Licensee is required to pay a royalty to both The Regents under this Agreement and the unaffiliated third party under that separate license agreement in order to practice Licensed Methods, and to make, use, Sell, offer to Sell or import Licensed Products, and the combined earned royalty due all the parties exceeds **[*]**, and the Net Sales amount has been allocated to the Licensed Product portion of the Combination Product pursuant to Subparagraph 1.14.5, then the Earned Royalty to be paid to The Regents under this Agreement by Licensee shall be reduced by an amount equal to **[*]** of the combined earned royalty rate due to The Regents and the unaffiliated third party. However, in no

event shall the amount paid to The Regents be reduced below **[*]** of the original Earned Royalty amount due The Regents on Net Sales of the Combination Product calculated without regard to Subparagraph 1.14.5 and without regard to this Paragraph 9.3.

9.4 Licensee will also pay to The Regents a minimum annual royalty of **[*]** for the life of Patent Rights, beginning with the year of the first Sale of Licensed Product, but no later than calendar year 2015. The minimum annual royalty will be paid to The Regents by February 28 of each year and will be credited against the Earned Royalty due for the calendar year in which the minimum payment was made. However, if the year of the first Sale is earlier than calendar year 2015, then Licensee's obligation to pay the minimum annual royalty will be pro-rated for the number of months remaining in that calendar year when Sales commence and will be due the following February 28 (along with the minimum annual royalty payment for that year), to allow for crediting of the pro-rated year's Earned Royalties.

10 MILESTONE PAYMENTS

10.1 With respect to each Licensed Product, Licensee will pay to The Regents the following non-refundable, non-creditable amounts:

10.1.1 **[*]** upon the first **[*]**;

10.1.2 **[*]** upon first **[*]**;

10.1.3 **[*]** upon first **[*]**;

10.1.4 **[*]** upon the first **[*]**;

10.1.5 **[*]** upon first **[*]**; *provided that* such payment shall be **[*]** upon **[*]** for each **[*]**.

10.2 For the avoidance of doubt, each of the milestone payments set forth in Section 10.1 above will be payable with respect to each different Licensed Product, but shall be payable only once with respect to such Licensed Product. Furthermore, each such milestone payment will be payable regardless of whether the applicable milestone event has been achieved by Licensee or any Affiliate, Joint Venture, or Sublicensee.

10.3 All milestone payments are due to The Regents within thirty (30) days of the occurrence of the applicable milestone event.

11 DUE DILIGENCE

11.1 Licensee, upon execution of this Agreement, will diligently proceed with the development, manufacture and (if required regulatory approvals are obtained) Sale of Licensed Products and will earnestly and diligently market the same after execution of this Agreement and in quantities sufficient to meet the market demands therefor, all using Commercially Reasonable Efforts.

11.2 Licensee will use Commercially Reasonable Efforts to obtain all necessary governmental approvals in each country where Licensed Products are intended to be manufactured, used, Sold, offered for Sale or imported; Licensee shall not make any Sale of a Licensed Product in a country without obtaining all necessary governmental approvals for the Sale in such country.

11.3 Licensee will:

11.3.1 **[*]** from the Effective Date;

11.3.2 **[*]** within **[*]** from the Effective Date;

11.3.3 **[*]** within **[*]** from the Effective Date;

11.3.4 **[*]** within **[*]** of **[*]**; and

11.3.5 **[*]** for Licensed Products **[*]** at any time during the exclusive period of this Agreement.

11.4 If Licensee does not perform any of the above milestone events under Subparagraphs 11.3.1 through 11.3.4 within the specified time, and Licensee can demonstrate with supporting documentation its Commercially Reasonable efforts to meet such milestones, then The Regents agrees to extend such milestone for one (1) year upon payment of an extension fee of **[*]**. Additional one (1) year extensions are available for any milestone provided that Licensee can continue to demonstrate its Commercially Reasonable efforts with supporting documentation and pays an additional extension fee of **[*]**.

11.5 If Licensee does not perform any of the above provisions in Section 11.3 within the specified time, and cannot demonstrate its Commercially Reasonable efforts to achieve such milestone (based on The Regents' objective, good faith assessment of Licensee's demonstration and supporting documentation), and *provided that* such failure is not due to matters outside of Licensee's control, then The Regents has the right and option to either terminate this Agreement or reduce the exclusive license granted to Licensee to a nonexclusive license subject to and in accordance with Paragraph 11.7 below. This right, if exercised by The Regents, supersedes the rights granted in Article 2 (Grant).

11.6 In addition to the obligations set forth above, Licensee shall **[*]** Licensed Products during the first two (2) years of this Agreement.

11.7 If Licensee fails to comply with the spending requirement set forth in Paragraph 11.5, then The Regents has the right and option to either terminate this Agreement or reduce the exclusive license granted to Licensee to a nonexclusive license. This right, if exercised by The Regents, supersedes the rights granted in Article 2 (Grant).

11.8 To exercise either the right to terminate this Agreement or to reduce the exclusive license granted to Licensee to a non-exclusive license for lack of diligence required in this Article 11 (Due Diligence), The Regents will give Licensee written notice of the deficiency. Licensee thereafter has sixty (60) days to cure the deficiency. If The Regents

has not received written tangible evidence satisfactory to The Regents that the deficiency has been cured by the end of the sixty (60)-day period, then The Regents may, at its option, terminate this Agreement immediately without the obligation to provide sixty (60) days' notice as set forth in Article 15 (Termination by The Regents) or reduce the exclusive license granted to Licensee to a non-exclusive license by giving written notice to Licensee.

12 PROGRESS AND ROYALTY REPORTS

12.1 Beginning on **March 31, 2008** and semi-annually thereafter, Licensee will submit to The Regents a written progress report as described in Paragraph 12.2 below covering Licensee's (and any Affiliates', Joint Ventures', or Sublicensee's) activities related to the development and testing of all Licensed Products and related to the obtaining of the governmental approvals necessary for marketing and the activities required and undertaken in order to meet the diligence requirements set forth in Article 11 (Due Diligence). Progress reports are required for each Licensed Product until the first Sale or other exploitation of that Licensed Product occurs in the United States and shall be again required if Sales of such Licensed Product are suspended or discontinued.

12.2 Progress reports submitted under Paragraph 12.1 shall include, but are not limited to, a reasonably detailed summary of the following topics so that The Regents will be able to determine the progress of the development of Licensed Products and will also be able to determine whether or not Licensee has met its diligence obligations set forth in Article 11 (Due Diligence) above:

12.2.1 summary of work completed as of the submission date of the progress report;

12.2.2 key scientific discoveries as of the submission date of the progress report;

12.2.3 summary of work in progress as of the submission date of the progress report;

12.2.4 current schedule of anticipated events and milestones, including those event and milestones specified in Article 11 (Due Diligence);

12.2.5 market plans for introduction of Licensed Products including the anticipated and actual market introduction dates of each Licensed Product;

12.2.6 Sublicensees' activities relating to the above items, if there are any Sublicensees;

12.2.7 a summary of resources (dollar value) spent in the reporting period; and

12.2.8 Licensee's progress in developing any New Licensed Products elected for commercial development by Licensee pursuant to Section 4 of this Agreement.

12.3 If Licensee fails to submit a timely progress report to The Regents, then The Regents will be entitled to terminate this Agreement, if Licensee fails to cure such failure within the cure period set forth in Section 15 after notice. If either party terminates this Agreement

before any Licensed Products are Sold or before this Agreement's expiration, then a final progress report covering the period prior to termination must be submitted within thirty (30) days of termination or expiration.

12.4 Licensee has a continuing responsibility to keep The Regents informed of the business entity status (small business entity status or large business entity status as defined by the United States Patent and Trademark Office) of itself, any Affiliates, Joint Ventures, or Sublicensees. Licensee will notify The Regents of any change of its status or that of any Affiliate, Joint Venture, or Sublicensee within thirty (30) days of the change in status.

12.5 Licensee will report to The Regents the date of first Sale or other exploitation of a Licensed Product in each country in its first progress and royalty reports following such first Sale of a Licensed Product.

12.6 Beginning with the earlier of (i) the first Sale or other exploitation of a Licensed Product or (ii) the first transaction that results in Sublicense Fees accruing to The Regents, Licensee will make quarterly royalty and Sublicensee Fee reports to The Regents on or before each February 28 (for the quarter ending December 31), May 31 (for the quarter ending March 31), August 31 (for the quarter ending June 30) and November 30 (for the quarter ending September 30) of each year. Each royalty and Sublicensee Fee report will cover Licensee's most recently completed calendar quarter and will, at a minimum, show:

12.6.1 the gross invoice prices and Net Sales of Licensed Products Sold or otherwise commercially exploited (itemizing the applicable gross proceeds and any deductions therefrom), and any Attributed Income (itemizing the applicable gross proceeds and any deductions therefrom) due to the Licensee;

12.6.2 the quantity of each type of Licensed Product Sold or otherwise commercially exploited in the U.S.;

12.6.3 the quantity of each Licensed Product made in the U.S. but Sold or otherwise commercially exploited outside the U.S.;

12.6.4 the Earned Royalties, in United States dollars, payable with respect to Net Sales;

12.6.5 the Sublicense Fees, in United States dollars, payable with respect to Attributed Income;

12.6.6 the method, used to calculate the Earned Royalty, specifying all deductions taken and the dollar amount of each such deduction;

12.6.7 the exchange rates used, if any;

12.6.8 the amount of the cash and the amount of the cash equivalent of any non-cash consideration including the method used to calculate the non-cash consideration; and

12.6.9 any other information reasonably necessary to confirm Licensee's calculation of its financial obligations hereunder.

12.7 If no Sales of Licensed Products have been made and no Licensed Products have been otherwise commercially exploited and no Attributed Income is due to Licensee during any reporting period, then a statement to this effect must be provided by Licensee in the immediately subsequent royalty and Sublicense Fee report.

13 BOOKS AND RECORDS

13.1 Licensee will keep accurate books and records showing all Licensed Product under development, manufactured, used, offered for Sale, imported, Sold and or otherwise commercially exploited; all Net Sales, all Attributed Income; and all sublicenses granted under the terms of this Agreement. Such books and records will be preserved for at least five (5) years after the date of the payment to which they pertain and will be open to examination by representatives or agents of The Regents during regular business hours to determine their accuracy and assess Licensee's compliance with the terms of this Agreement. Any such examination shall be on reasonably prior notice, and shall be conducted pursuant to a typical confidentiality agreement and in a manner that does not materially disrupt the business of Licensee and is subject to all reasonable conditions relating to access and activities while on Licensee's premises.

13.2 The Regents shall pay the fees and expenses of such examination. lf, however, an error in royalties of more than five percent (5%) of the total royalties due for any year is discovered in any examination, then Licensee shall bear the fees and expenses of such examination and shall remit such underpayment to The Regents within thirty (30) days of the examination results.

14 LIFE OF THE AGREEMENT

14.1 Unless otherwise terminated by operation of law, Paragraph 14.2, or by acts of the parties in accordance with the terms of this Agreement, this Agreement will remain in effect from the Effective Date until the expiration or abandonment of the last of the Patent Rights licensed hereunder.

14.2 This Agreement will automatically terminate without the obligation to provide sixty (60) days' notice as set forth in Article 15 (Termination By The Regents) upon the filing of a petition for relief under the United States Bankruptcy Code by or against Licensee as a debtor or alleged debtor.

14.3 This Agreement will automatically terminate immediately without the obligation to provide sixty (60) days' notice as set forth in Article 15 (Termination By The Regents) if Licensee files a claim in a legal action that seeks to declare that any portion of Regents Patent Rights is invalid or unenforceable where the filing is by the Licensee, a third party on behalf of the Licensee, or a third party at the written urging of the Licensee. In the event a declaratory judgment results from such a filing, the Licensee shall pay all attorneys fees incurred by The Regents for counsel retained to defend The Regents against such declaratory judgment.

14.4 Any termination or expiration of this Agreement will not affect the rights and obligations set forth in the following Articles:

Article I	Definitions
Paragraph 5.8	Late Payments
Article 6	License Issue Fee
Article 8	Payments on Sublicenses
Paragraphs 9.1 and 9.3	Earned Royalties and Minimum Annual Royalties
Article 13	Books and Records
Article 14	Life of the Agreement
Article 17	Disposition of Licensed Products on Hand Upon Termination or Expiration
Article 18	Use of Names and Trademarks
Article 19	Limited Warranty
Article 20	Limitation of Liability
Paragraphs 21.4 & 21.5	Patent Prosecution and Maintenance
Article 24	Indemnification
Article 25	Notices
Article 29	Governing Laws; Venue; Attorneys Fees
Article 32	Confidentiality

14.5 The termination or expiration of this Agreement will not relieve Licensee of its obligation to pay any fees, royalties or other payments owed to The Regents at the time of such termination or expiration and will not impair any accrued right of The Regents, including the right to receive Earned Royalties in accordance with Articles 8 (Payments on Sublicenses), 9 (Earned Royalties and Minimum Annual Royalties) and 17 (Disposition of Licensed Products Upon Termination or Expiration).

15 TERMINATION BY THE REGENTS

If Licensee fails to perform or violates any material term of this Agreement, then The Regents may give written notice of such default ("Notice of Default") to Licensee. If Licensee fails to repair such material default within sixty (60) days after the effective date of such notice, then The Regents will have the right to immediately terminate this Agreement and its licenses by providing a written notice of termination ("Notice of Termination") to Licensee.

16 TERMINATION BY LICENSEE

Licensee has the right at any time to terminate this Agreement by providing a Notice of Termination to The Regents. Moreover, Licensee will be entitled to terminate the rights under Patent Rights on a country-by-country basis by giving notice in writing to The Regents. Termination of this Agreement (but not termination of any patents or patent applications under Patent Rights, which termination is subject to Paragraph 21.5) will be effective sixty (60) days from the effective date of such notice.

17 DISPOSITION OF LICENSED PRODUCTS UPON TERMINATION OR EXPIRATION

17.1 Upon early termination (but not expiration) of this Agreement, within a period of one hundred and twenty (120) days after the date of termination, Licensee is entitled to dispose of all previously made or partially made Licensed Product, but no more, provided that the Sale or use of such Licensed Product is subject to the terms of this Agreement, including, but not limited to, the rendering of reports and payment of Earned Royalties, Sublicense Fees and any other payments therefor required under this Agreement. Licensee will not otherwise use or practice the Patent Rights, or practice the Licensed Method, in a manner constituting patent infringement after the date of early termination.

17.2 If applicable Patent Rights exist at the time of any making, Sale, offer for Sale, or import of a Licensed Product or the time of any Sale, offer for Sale, then Earned Royalties shall be paid at the times provided herein and royalty reports shall be rendered in connection therewith, notwithstanding the absence of applicable Patent Rights with respect to such Licensed Product at any later time. Otherwise, no Earned Royalties shall be paid on the Sales of such product. Any fees or other payments accrued and owed to The Regents at the time of expiration of the Agreement not based on the Sales of a Licensed Product will be paid to The Regents at the time such fee or other payment would have been due had this Agreement not expired.

18 USE OF NAMES AND TRADEMARKS

Nothing contained in this Agreement will be construed as conferring any right to either party to use in advertising, publicity or other promotional activities any name, trade name, trademark or other designation of the other party (including a contraction, abbreviation or simulation of any of the foregoing). Without Licensee's consent case-by-case, The Regents may list Licensee's name as a licensee of technology from The Regents without further identifying the technology. Unless required by law or unless consented to in writing by the Director, Office of Technology Management of the University of California, San Francisco, the use by Licensee of the name "The Regents of the University of California" or the name of any campus of the University of California in advertising, publicity or other promotional activities is expressly prohibited.

19 LIMITED WARRANTY

19.1 The Regents warrants to Licensee that it has the lawful right to grant the license rights granted under this Agreement, that it believes it owns the Patent Rights and that, to the knowledge of the licensing professional responsible for administration of this Agreement after reasonable investigation and inquiry and as of the Effective Date, it has not granted to any third party any license rights in the licensed Field of Use under any of the Patent Rights.

19.2 Except as expressly set forth in this Agreement, this license and the associated Inventions, Patent Rights, Licensed Products, and Licensed Methods are provided by The Regents WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY OF ANY KIND, EXPRESS OR IMPLIED. THE REGENTS MAKES NO EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY THAT THE INVENTION, PATENT RIGHTS,

LICENSED PRODUCTS, OR LICENSED METHODS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS.

19.3 This Agreement does not:

19.3.1 express or imply a warranty or representation as to the validity, enforceability, or scope of any Patent Rights; or

19.3.2 express or imply a warranty or representation that anything made, used, Sold, offered for Sale or imported or otherwise exploited under any license granted in this Agreement is or will be free from infringement of patents, copyrights, or other rights of third parties; or

19.3.3 obligate The Regents to bring or prosecute actions or suits against third parties for patent infringement except as provided in Article 23 (Patent Infringement); or

19.3.4 confer by implication, estoppel or otherwise any license or rights under any patents or other rights of The Regents other than Patent Rights, regardless of whether such patents are dominant or subordinate to Patent Rights; or

19.3.5 obligate The Regents to furnish any New Developments, know-how, technology or information not provided in Patent Rights.

20 LIMITATION OF LIABILITY

THE REGENTS AND LICENSEE WILL NOT BE LIABLE FOR ANY LOST PROFITS, COSTS OF PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT OR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR OTHER SPECIAL DAMAGES SUFFERED BY LICENSEE, SUBLICENSEES, JOINT VENTURES, OR AFFILIATES OR THE REGENTS ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY) EVEN IF THE REGENTS OR LICENSEE (AS APPLICABLE) HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, PROVIDED THAT THE FOREGOING PROVISION SHALL NOT BE CONSTRUED TO LIMIT LICENSEE'S INDEMNIFICATION OBLIGATION UNDER THIS AGREEMENT.

21 PATENT PROSECUTION AND MAINTENANCE

21.1 As long as Licensee has paid Patent Prosecution Costs as provided for in this Article 21 (Patent Prosecution and Maintenance), The Regents will diligently prosecute and maintain the United States and foreign patents comprising the Patent Rights using counsel of its choice selected from the list of law firms previously approved by The Regents and reasonably acceptable to Licensee. The Regents' counsel will take instructions only from The Regents. The Regents will provide Licensee with copies of all relevant documentation so that Licensee will be informed of the continuing

prosecution and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if Licensee has not commented upon such documentation in a reasonable time for The Regents to sufficiently consider Licensee's comments prior to a deadline with the relevant government patent office, or The Regents must act to preserve the Patent Rights, The Regents will be free to respond without consideration of Licensee's comments, if any. Licensee agrees to keep this documentation confidential as provided for in Article 32 (Confidentiality).

21.2 The Regents shall use reasonable efforts to amend any patent application to include claims reasonably requested by Licensee to protect the products and services contemplated to be Sold, or the Licensed Method to be practiced, under this Agreement.

21.3 Licensee will apply for an extension of the term of any patent included within the Patent Rights if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984. Licensee shall prepare all documents and The Regents agrees to execute the documents and to take additional action as Licensee reasonably requests in connection therewith. Licensee shall be liable for all costs relating to such application.

21.4 Licensee will bear the costs of preparing, filing, prosecuting and maintaining all United States patents and patent applications contemplated by this Agreement ("Patent Prosecution Costs"). Patent Prosecution Costs billed by The Regents' counsel will be rebilled to Licensee and are due within thirty (30) days of rebilling by The Regents. These Patent Prosecution Costs will include, without limitation, patent prosecution costs for the Inventions incurred by The Regents prior to the execution of this Agreement and any patent prosecution costs that may be incurred for patentability opinions, re-examination, re-issue, interferences, oppositions or inventorship determinations. Prior Patent Prosecution Costs will be due upon execution of this Agreement and billing by The Regents and as of the Effective Date totals **[*]**.

21.5 Licensee will be obligated to pay any Patent Prosecution Costs incurred during the three (3)-month period after receipt by either party of a Notice of Termination, even if the invoices for such Patent Prosecution Costs are received by Licensee after the end of the three (3)-month period following receipt of a Notice of Termination. Licensee may terminate its obligation to pay Patent Prosecution Costs with respect to any given patent application or patent under Patent Rights in any or all designated countries upon three (3)-months' written notice to The Regents. The Regents may continue prosecution and/or maintenance of such application(s) or patent(s) at its sole discretion and expense, provided, however, that Licensee will have no further right or licenses thereunder. Non-payment of Patent Prosecution Costs may be deemed by The Regents as an election by Licensee not to maintain such application(s) or patent(s).

21.6 The Regents may file, prosecute or maintain patent applications or patents at its own expense in any country in which Licensee has not elected to file, prosecute or maintain patent applications or patents in accordance with this Article 21 (Patent Prosecution and Maintenance) and those applications, resultant patents and patents will not be subject to this Agreement.

22 PATENT MARKING

Licensee will mark all Licensed Products made, used or Sold under the terms of this Agreement or their containers in accordance with the applicable patent marking laws.

23 PATENT INFRINGEMENT

23.1 In the event that The Regents (to the extent of the actual knowledge of the licensing professional responsible for the administration of this Agreement) or Licensee learns of infringement of potential commercial significance of any patent licensed under this Agreement, the knowledgeable party will provide the other (i) with written notice of such infringement and (ii) with any evidence of such infringement available to it (the "**Infringement Notice**"). During the period in which, and in the jurisdiction where, Licensee has exclusive rights under this Agreement, neither The Regents nor Licensee will notify a possible infringer of infringement or put such infringer on notice of the existence of any Patent Rights without first obtaining consent of the other.. If Licensee puts such infringer on notice of the existence of any Patent Rights with respect to such infringement without first obtaining the written consent of The Regents and if a declaratory judgment action is filed by such infringer against The Regents, then Licensee's right to initiate a suit against such infringer for infringement under Paragraph 23.2 below will terminate immediately without the obligation of The Regents to provide notice to Licensee. Both The Regents and Licensee will use their diligent efforts to cooperate with each other reasonably and in good faith to terminate such infringement without litigation.

23.2 If infringing activity of potential commercial significance by the infringer has not been abated within ninety (90) days following the date the Infringement Notice is given, then Licensee may institute suit for patent infringement against the infringer. The Regents may voluntarily join such suit at its own expense, but may not otherwise commence suit against the infringer for the acts of infringement that are the subject of Licensee's suit or any judgment rendered in that suit. Licensee may not join The Regents as a party in a suit initiated by Licensee without The Regents' prior written consent. If, in a suit initiated by Licensee, The Regents is involuntarily joined other than by Licensee, then Licensee will pay any costs incurred by The Regents arising out of such suit, including but not limited to, any legal fees of counsel that The Regents selects and retains to represent it in the suit.

23.3 If, within a hundred and twenty (120) days following the date the Infringement Notice takes effect, infringing activity of potential commercial significance by the infringer has not been abated and if Licensee has not brought suit against the infringer, then The Regents may institute suit for patent infringement against the infringer. If The Regents institutes such suit, then Licensee may not join such suit without The Regents' consent and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of The Regents' suit or any judgment rendered in that suit.

23.4 Notwithstanding anything to the contrary in this Agreement, in the event that the infringement or potential infringement pertains to an issued patent included within the

Patent Rights and written notice is given under the Drug Price Competition and Patent Term Restoration Act of 1984 (and/or foreign counterparts of this Law), then the party in receipt of such notice under the Act (in the case of The Regents to the extent of the actual knowledge of the licensing officer responsible for the administration of this Agreement) shall provide the Infringement Notice to the other party promptly. If the time period is such that Licensee will lose the right to pursue legal remedy for infringement by not notifying a third party or by not filing suit, the notification period and the time period to file suit will be accelerated to within forty-five (45) days of the date of such notice under the Act to either party.

23.5 Any recovery or settlement received in connection with any suit will first be shared by The Regents and Licensee equally to cover any litigation costs each incurred and next shall be paid to The Regents or Licensee to cover any litigation costs it incurred in excess of the litigation costs of the other. In any suit initiated by Licensee, any recovery in excess of litigation costs will be shared between Licensee and The Regents as follows: (a) for any recovery other than amounts paid for willful infringement: (i) The Regents will receive **[*]** of the net recovery if The Regents was not a party in the litigation and did not incur any out-of-pocket and invoiced litigation costs that were not reimbursed by Licensee (or its designee) prior to Licensee's receipt of the recovery, (ii) The Regents will receive **[*]** of the net recovery if The Regents was a party in the litigation whether joined as a party under the provisions of Paragraph 23.2 or otherwise, but The Regents did not incur any out-of-pocket and invoiced litigation costs that were not reimbursed by Licensee (or its designee) prior to any settlement or judgment resulting in Licensee's receipt of the recovery, and (iii) The Regents will receive **[*]** of the recovery if The Regents incurred out-of-pocket and invoiced litigation costs in connection with the litigation in amounts reasonably equal to at least half of the out-of-pocket and invoiced costs incurred by Licensee; and (b) for any recovery for willful infringement, The Regents will receive **[*]** of the recovery. In any suit initiated by The Regents, any recovery in excess of litigation costs will belong to The Regents. The Regents and Licensee agree to be bound by all determinations of patent infringement, validity and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Article 23 (Patent Infringement).

23.6 Any agreement made by Licensee for purposes of settling litigation or other dispute shall comply with the requirements of Article 3 (Sublicenses) of this Agreement.

23.7 Each party will cooperate with the other in litigation proceedings instituted hereunder but at the expense of the party who initiated the suit (unless such suit is being jointly prosecuted by the parties).

23.8 Any litigation proceedings will be controlled by the party bringing the suit, except that The Regents may be represented by counsel of its choice in any suit brought by Licensee.

24 INDEMNIFICATION

24.1 Licensee will, and will require its Sublicensees to, indemnify, hold harmless and defend The Regents, the sponsors of the research that led to the Inventions, and the inventors of

any inventions claimed in patents or patent applications under Patent Rights (including the Licensed Products, and Licensed Methods contemplated thereunder) and their employers, and the officers, employees and agents of any of the foregoing, against any and all claims, suits, losses, damage, costs, fees and expenses resulting from, or arising out of, the exercise of this license or any sublicense. This indemnification will include, but not be limited to, any product liability. If The Regents reasonably believes that there will be a conflict of interest or it will not otherwise be adequately represented by counsel chosen by Licensee to defend The Regents in accordance with this Paragraph 24.1, then The Regents may retain counsel of its choice to represent it. If The Regents retains such counsel due to a conflict of interest, the Licensee will pay all expenses for such representation. If The Regents retains such counsel because it believes it will not otherwise be adequately represented by counsel chosen by the Licensee, then The Regents will pay all expenses for such representation. If The Regents retains such counsel, Licensee will not be responsible for indemnifying The Regents for any losses, damage, costs, fees and expenses that result from inadequate defense provided by such counsel.

24.2 During the term of this Agreement and for three (3) years following its termination, the Licensee, at its sole cost and expense, will insure its activities in connection with any work performed hereunder and will obtain and maintain the following insurance (or an equivalent program of self-insurance):

24.2.1 Comprehensive or commercial form general liability insurance (contractual liability included) with limits as follows:

Each Occurrence	$	1,000,000
Personal and Advertising Injury	$	1,000,000
General Aggregate (commercial form only)	$	2,000,000

24.2.2 Worker’s Compensation as legally required in the jurisdiction in which Licensee is doing business.

24.3 Notwithstanding Paragraph 24.2, no later than the earlier of: i) sixty (60) days before the anticipated date of market introduction of any Licensed Product; or ii) sixty (60) days before the first use of any Licensed Product in a human under this Agreement, Licensee, at its sole cost and expense, shall insure its activities in connection with the work under this Agreement and obtain, keep in force and maintain the following insurance (or an equivalent program of self-insurance) during the term of this Agreement and for three (3) years following its termination:

24.3.1 Comprehensive or Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

Each Occurrence	$	5,000,000
Products/Completed Operations Aggregate	$	10,000,000
Personal and Advertising Injury	$	5,000,000
General Aggregate (commercial form only)	$	10,000,000

24.3.2 Worker’s Compensation as legally required in the jurisdiction in which Licensee is doing business.

24.4 If the insurance under Paragraphs 24.2 and 24.3 is written on a claims-made form, it shall continue for three (3) years following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement.

24.5 The coverage and limits referred to in Paragraph 24.2.1 and 24.2.2 above will not in any way limit the liability of Licensee under this Article 24 (Indemnification). Upon the execution of this Agreement, Licensee will furnish The Regents with certificates of insurance evidencing compliance with all requirements. Such certificates will:

24.5.1 Provide for thirty (30) days’ (ten (10) days for non-payment of premium) advance written notice to The Regents of any cancellation of insurance coverage; Licensee will promptly notify The Regents of any material modification of the insurance coverage;

24.5.2 Indicate that The Regents has been endorsed as an additional insured under the coverage described above in Paragraph 24.2.1; and

24.5.3 Include a provision that the coverage will be primary and will not participate with, nor will be excess over, any valid and collectable insurance or program of self-insurance maintained by The Regents.

24.6 The Regents will promptly notify Licensee in writing of any claim or suit brought against The Regents for which The Regents intends to invoke the provisions of this Article 24 (Indemnification). Licensee will keep The Regents informed of its defense of any claims pursuant to this Article 24 (Indemnification).

25 NOTICES

25.1 Any notice or payment required to be given to either party under this Agreement will be in writing and will be deemed to have been properly given and to be effective as of the date specified below if delivered to the respective address given below or to another address as designated by written notice given to the other party: on the date of delivery if delivered in person; on the date of mailing if mailed by first-class certified mail, postage paid; or on the date of mailing if mailed by any global express carrier service that requires the recipient to sign the documents demonstrating the delivery of such notice or payment.

In the case of Licensee: Chief Executive Officer
BioProtection Systems Corporation
2901 South Loop Drive, Suite 3360
Ames, IA 50010

In the case of The Regents: Director

Office of Technology Management
185 Berry Street, Suite 4603
San Francisco, California 94107
RE: **[*]**

26 ASSIGNABILITY

This Agreement is personal to the Licensee. The Licensee may not assign or transfer this Agreement, including by merger, operation of law, or otherwise, without The Regents' prior written consent, except that such consent will not be required in the case of assignment or transfer to an Affiliate or to a party that succeeds to all or substantially all of Licensee's business or assets relating to this Agreement, whether by sale, merger, operation of law or otherwise, provided that such assignee or transferee promptly agrees to be bound by the terms and conditions of this Agreement and signs The Regents' standard substitution of party letter (the form of which is attached hereto as **Appendix B**). Any attempted assignment by the Licensee in violation of this Article 26 (Assignment) will be null and void. This Agreement is binding upon and will inure to the benefit of The Regents, its successors and assigns.

27 WAIVER

No waiver by either party of any breach or default of any of the agreements contained herein will be deemed a waiver as to any subsequent and/or similar breach or default. No waiver will be valid or binding upon the parties unless made in writing and signed by a duly authorized officer of each party.

28 FORCE MAJEURE

28.1 Except for Licensee's obligation to make any payments to The Regents hereunder, the parties shall not be responsible for any failure to perform due to the occurrence of any events beyond their reasonable control which render their performance impossible or onerous, including, but not limited to: accidents (environmental, toxic spill, etc.); acts of God; biological or nuclear incidents; casualties; earthquakes; fires; floods; governmental acts; orders or restrictions; inability to obtain suitable and sufficient labor, transportation, fuel and materials; local, national or state emergency; power failure and power outages; acts of terrorism; strike; and war.

28.2 Either party to this Agreement, however, will have the right to terminate this Agreement upon thirty (30) days' prior written notice if either party is unable to fulfill its obligations under this Agreement due to any of the causes specified in Paragraph 28.1 for a period of one (1) year.

29 GOVERNING LAWS; VENUE; ATTORNEYS' FEES

29.1 THIS AGREEMENT WILL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, excluding any choice of law rules that would direct the application of the laws of another jurisdiction and without regard to which party drafted particular provisions of this

Agreement, but the scope and validity of any patent or patent application will be governed by the applicable laws of the country of such patent or patent application.

29.2 Any legal action brought by the parties hereto relating to this Agreement will be conducted in San Francisco, California,

29.3 The prevailing party in any suit related to this Agreement will be entitled to recover its reasonable attorneys' fees in addition to its costs and necessary disbursements.

30 GOVERNMENT APPROVAL OR REGISTRATION

If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee will assume all legal obligations to do so. Licensee will notify The Regents if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. Licensee will make all necessary filings and pay all costs including fees, penalties and all other out-of-pocket costs associated with such reporting or approval process.

31 COMPLIANCE WITH LAWS

Licensee shall comply with all applicable international, national, state, regional and local laws and regulations in performing its obligations hereunder and in its use, manufacture, Sale or import of the Licensed Products, or practice of the Licensed Method. Licensee will observe all applicable United States and foreign laws with respect to the transfer of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations. Licensee shall manufacture Licensed Products and practice the Licensed Method in compliance with applicable government importation laws and regulations of a particular country for Licensed Products made outside the particular country in which such Licensed Products are used, Sold or otherwise exploited.

32 CONFIDENTIALITY

32.1 Licensee and The Regents will treat and maintain the other party's proprietary business, patent prosecution, software, engineering drawings, process and technical information and other proprietary information, including the negotiated terms of this Agreement and any progress reports and royalty reports and any sublicense agreement issued pursuant to this Agreement ("Proprietary Information") in confidence using at least the same degree of care as the receiving party uses to protect its own proprietary information of a like nature from the date of disclosure until five (5) years after the termination or expiration of this Agreement.

32.2 Each of Licensee and The Regents may use and disclose the other party's Proprietary Information to its respective employees, agents, consultants, contractors and, in the case of Licensee, its Sublicensees, provided that such parties are bound by a like duty of confidentiality as that found in this Article 32 (Confidentiality). Notwithstanding anything to the contrary contained in this Agreement, The Regents may release this Agreement or any sublicense, including any terms thereof, and information regarding

royalty payments or other income received in connection with this Agreement to the inventors, senior administrative officials employed by The Regents and individual Regents upon their request. If such release is made, The Regents will request that such terms be kept in confidence in accordance with the provisions of this Article 32 (Confidentiality). In addition, notwithstanding anything to the contrary in this Agreement, if a third party inquires whether a license to Patent Rights is available, then The Regents may disclose the existence of this Agreement and the extent of the grant in Articles 2 (Grant) and 3 (Sublicenses) and related definitions to such third party, but will not disclose the name of Licensee unless Licensee has already made such disclosure publicly. Further, Licensee may disclose the existence and terms of this Agreement: (a) in confidence to its directors, officers, investors and professional service providers and to bona fide prospective investors, acquirors, strategic partners, or merger partners and their respective professional advisors; and (b) publicly to the extent required by applicable law or regulation, and provided that Licensee uses reasonable efforts to obtain an order protecting the confidentiality of sensitive technical or financial terms hereof to the extent such order is legally available.

32.3 All written Proprietary Information disclosed by a party will be labeled or marked confidential or proprietary. If the Proprietary Information is orally disclosed, it will be reduced to writing or some other physically tangible form, marked and labeled as confidential or proprietary by the disclosing party and delivered to the receiving party within thirty (30) days after the oral disclosure.

32.4 Nothing contained herein will restrict or impair, in any way, the right of Licensee or The Regents to use or disclose any Proprietary Information of the other party:

32.4.1 that recipient can demonstrate by written records was previously known to it prior to its disclosure by the disclosing party;

32.4.2 that recipient can demonstrate by written records is now, or becomes in the future, public knowledge other than through acts or omissions of recipient;

32.4.3 that recipient can demonstrate by written records was obtained lawfully and without restrictions on the recipient from sources independent of the disclosing party; and

32.4.4 that The Regents is required to disclose pursuant to the California Public Records Act or other applicable law.

Each of Licensee or The Regents also may disclose the other party's Proprietary Information to the extent that such Proprietary Information is required to be disclosed (i) to a governmental entity or agency in connection with seeking any governmental or regulatory approval, governmental audit, or other governmental contractual requirement or (ii) by law or court order, provided that the recipient uses reasonable efforts to give the party owning the Proprietary Information sufficient notice of such required disclosure to allow the party owning the Proprietary Information reasonable opportunity to object to, and to take legal action to prevent, such disclosure.

32.5 Upon termination of this Agreement, Licensee and The Regents will destroy or return any of the disclosing party's Proprietary Information in its possession within fifteen (15) days following the termination of this Agreement. Licensee and The Regents will provide each other, within thirty (30) days following termination, with written notice that such Proprietary Information has been returned or destroyed. Each party may, however, retain one copy of such Proprietary Information for archival purposes in non-working files.

33 MISCELLANEOUS

33.1 The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

33.2 This Agreement is not binding on the parties until it has been signed below on behalf of each party. It is then effective as of the Effective Date.

33.3 No amendment or modification of this Agreement is valid or binding on the parties unless made in writing and signed on behalf of each party.

33.4 This Agreement embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof.

33.5 In case any of the provisions contained in this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement and this Agreement will be construed as if such invalid, illegal or unenforceable provisions had never been contained in it

33.6 No provisions of this Agreement are intended or shall be construed to confer upon or give to any person or entity other than The Regents and Licensee any rights, remedies or other benefits under, or by reason of, this Agreement.

33.7 In performing their respective duties under this Agreement, each of the parties will be operating as an independent contractor. Nothing contained herein will in any way constitute any association, partnership, or joint venture between the parties hereto, or be construed to evidence the intention of the parties to establish any such relationship. Neither party will have the power to bind the other party or incur obligations on the other party's behalf without the other party's prior written consent.

IN WITNESS WHEREOF, both The Regents and Licensee have executed this Agreement, in duplicate originals, by their respective and duly authorized officers on the day and year written.

Licensee		**The Regents of the University of California**	
By:	_____ (Signature)	By:	_____ (Signature)
Name:	Charles J. Link	Name:	Joel B. Kirschbaum
Title:	Chief Executive Officer	Title:	Director, UCSF Office of Technology Management
Date:	July 3, 2008	Date:	7/29/08

APPENDIX A

KNOW-HOW

1. **[*]**

2. **[*]**

3. **[*]**

APPENDIX B

UCSF Case Nos. **[*]**

CONSENT TO SUBSTITUTION OF PARTY

This substitution of parties ("Agreement") is effective this day of , 20 , among The Regents of the University of California ("The Regents), a California corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200 and acting through its Office of Technology Management, University of California San Francisco ("UCSF"), 185 Berry Street, Suite 4603, San Francisco, California 94107; BioProtection Systems Corporation, a Delaware corporation, having a principal place of business at 2901 South Loop Drive, Suite 3360, Ames, Iowa 50010-8646 ("BPS"); and [new licensee name] [("YYY")] a corporation, having a principal place of business at .

BACKGROUND

A. The Regents and BPS entered into a License Agreement effective (UC Control No. - -), entitled Recombinant Yellow Fever Virus as a Vaccine Vector ("License Agreement"), wherein BPS was granted certain rights.

B. BPS desires that [YYY] be substituted as Licensee (defined in the License Agreement) in place of BPS, and The Regents is agreeable to such substitution.

C. [YYY] has read the License Agreement and agrees to abide by its terms and conditions.

The parties agree as follows:

1. [YYY] assumes all liability and obligations under the License Agreement and is bound by all its terms in all respects as if it were the original Licensee of the License Agreement in place of BPS.

2. [YYY] is substituted for BPS, provided that [YYY] assumes all liability and obligations under the License Agreement as if [YYY] were the original party named as Licensee as of the effective date of the License Agreement.

3. The Regents releases BPS from all liability and obligations under the License Agreement arising before or after the effective date of this Agreement.

The parties have executed this Agreement in triplicate originals by their respective authorized officers on the following day and year.

BIOPROTECTION SYSTEMS CORPORATION

By: _____
(Signature)

Name: _____
(Please print)

Title: _____

Date: _____

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By: _____

Name: _____

Title: [Licensing Officer]
Office of Technology Management

Date: _____

[YYY] COMPANY

By: _____
(Signature)

Name: _____
(Please print)

Title: _____

Date: _____

SOLE LICENSE AGREEMENT FOR RECOMBINANT VESICULAR STOMATITIS VIRUS VACCINES FOR VIRAL HEMORRHAGIC FEVERS

BETWEEN:

HER MAJESTY THE QUEEN IN RIGHT OF CANADA,
as represented by the Minister of Health,
acting through the Public Health Agency of Canada

("Canada")

AND:

BIOPROTECTION SYSTEMS CORPORATION,
a company incorporated as a subchapter C corporation
under the laws of Delaware, having its registered office at
Iowa State University Research Park,
2901 South Loop Drive, Suite 3360, Ames, Iowa, USA 50010

("Company")

INTRODUCTION:

A. **WHEREAS** Canada is one of the major performers in Canada of vaccine research relating to viral hemorrhagic fever ("*VHF*") viruses;

B. **WHEREAS** Canada has developed the technology known as the "Recombinant vesicular stomatitis virus vaccine for viral hemorrhagic fevers";

C. **WHEREAS** the main features of the technology include [*];

D. **WHEREAS** the Company has requested a license from Canada to develop and ***Commercialize*** the technology;

E. **WHEREAS** Canada is willing to grant to the Company a license to develop and ***Commercialize*** the technology on the terms and conditions set out in this ***License Agreement***;

F. **WHEREAS** the fundamental principles underlying this ***License Agreement*** are that:

i) Canada surrenders its commercial self-interest to the Company; and

ii) In exchange, in good faith, the Company uses its discretion and experience in product development and regulatory affairs, its commercial resources and business savvy and, assuming that any relevant statutory, regulatory or administrative authorizations or permits for a vaccine product are obtained, its marketing, sale and distribution savvy for the benefit of both ***Parties***.

G. **WHEREAS** the salient elements of this ***License Agreement*** are:

i) Canada grants to the Company sole, worldwide, revocable and royalty-bearing license to make, use, improve, develop and ***Commercialize*** the technology in the field of prevention and prophylaxis against and treatment of VHF viruses in humans, whether before or after exposure;

ii) Canada will retain non-commercial rights in the technology, including rights to use and further develop the technology for educational and research purposes;

iii) The Company grants to Canada a non-exclusive and royalty-free license to make, use, manufacture and sell the VHF vaccine products developed by the Company in the exercise of the ***Licensed Rights***, in the event of a public health emergency:

iv) The Company will make good faith efforts to collaborate with Canada on [*] of the Company's basic research and development activities related to *VHF* virus vaccines; and

v) The ***Parties*** agree to maintain the confidentiality of each other's ***Confidential Information*** provided under this ***License Agreement***.

H. **WHEREAS** the expectations of the Parties are that the Company will use commercially reasonable efforts to develop a *VHF* vaccine and, assuming that any relevant and necessary statutory, regulatory and administrative authorizations or permits that may be required for a vaccine product are

obtained, ***Commercialize*** it; and

I. **WHEREAS** the Parties have agreed to their commercial relationship on the terms and conditions set out in this ***License Agreement***.

NOW THEREFORE in consideration of the premises, the terms and conditions hereinafter contained and other good and valuable consideration, the receipt of which is hereby acknowledged by each party, the Parties hereto covenant and agree as follows:

1.0 DEFINITIONS

1.1 **"Affiliate"**

means any corporation, subsidiary, partnership or other entity which the Company, directly or indirectly, controls (or has common control of) or which, directly or indirectly, controls the Company:

1.1.1 through the ownership of more than 50% of the voting share capital, and the votes attached to those securities are sufficient, if exercised, to elect a majority of the directors of the body corporate; or

1.1.2 otherwise has the possession, direct or indirect, of the powers to direct or cause the direction of the management or policies of a person or entity; whether through ownership of equity participation, voting securities, or beneficial interests; by contract, by agreement, or otherwise.

Identified in appendix D ("Affiliates") are the ***Affiliates*** of the Company In existence on the ***Execution Date***.

1.2 ***"Commercialization" or "Commercialize"***

means:

1.2.1 the commercial making, using, ***Sale*** or offering to sell;

1.2.2 of the products resulting from the exercise of the ***Licensed Rights***;

1.2.3 by the Company, its ***Affiliates*** or its sub-licensees;

1.2.4 in the ***Territory***;

1.2.5 within the ***Field of Use***; and

1.2.6 for the maximum commercial return to the Company and Canada in accordance with Article 4 (Exploitation of ***Licensed Rights***) including:

1.2.6.2 the Company obtaining any statutory, regulatory or administrative authorizations or permits that may be required in order for the Company to legally carry out all of its activities under the ***License Agreement***.

1.3 ***"Confidential Information"***

means, with respect to a ***Party***, all proprietary information of any type, or any part or portion thereof, that is disclosed by that ***Party*** to the other ***Party*** pursuant to this ***License Agreement***, whether or not such information is specifically marked or identified as confidential at the time of disclosure, which may include without limitation.

1.3.1 all scientific, technical, business, financial, legal, marketing or strategic information (including trade secrets and proprietary know-how);

1.3.2 all documented research, development, demonstration or engineering work, information that can be or is used to define a design or process or procure, produce, support or operate material and equipment, methods of production, regardless of its form:

1.3.3 all drawings, blueprints, patterns, plans, flow-charts, equipment, parts lists, software and procedures, specifications formulae, designs, technical data, descriptions, related instruction manuals, records and procedures;

1.3.4 information that is non-public, confidential, privileged or proprietary in nature.

which may have actual or potential economic value in part from not being known and may be positive (what works) or negative (what does not) information;

1.3.5 however fixed, stored, expressed or embodied (and includes, without limitation, samples, prototypes, specimens and derivatives);

1.3.6 and including information disclosed during discussions, meetings, tests, demonstrations, correspondence or otherwise.

1.4 ***"Confidentiality Agreements"***

means the agreements previously executed between the ***Parties*** on the 1st day of May, 2007, November 1, 2008, and the amending letter of April 14, 2010 respectively, and contained in Appendix B (***Confidentiality Agreements***).

1.5 "Dispute"

for purposes of Article 16 (Alternate Dispute Resolution (ADR)), and paragraph 17.17 (Forum Conveniens)

1.5.1 includes without limitation any controversy, conflict, claim, disagreement or difference of opinion arising out of the ***License Agreement***, (irrespective of whether it is premised on contract, tort or trust / equity), including, without limitation, any issues concerning the breach, interpretation, rectification, termination, performance, enforcement or validity of the ***License Agreement*** or the rights and liabilities of the ***Parties*** in relation to the ***License Agreement***;

1.5.2 irrespective of the fact that there is no arguable defence under the ***License Agreement***, or that the facts or law are undisputable and subject to judicial summary proceedings;

but ***Dispute*** does not encompass

1.5.3 any controversy, conflict, claim, disagreement or difference of opinion or the rights and liabilities of the ***Parties***

1.5.3.2 under any collateral or antecedent agreements independent of the ***License Agreement***; or

1.5.3.3 with any emanation of Her Majesty the Queen in Right of Canada, other than the Public Health Agency of Canada.

1.6 "Execution Date"

means the date on which the last signature is affixed to this ***License Agreement***.

1.7 "Field of Use"

means the application and use of the ***Licensed Rights*** only with products to be sold or used by the Company, or its ***Affiliates*** or sublicensees or marketed through specified trade channels in the field of prevention and prophylaxis against and treatment of VHF viruses in humans and for no other purposes whatsoever.

1.8 "Generally Accepted Accounted Principles (GAAP)"

means, at any time, accounting principles generally accepted in Canada as recommended in the Handbook of the Canadian Institute of Chartered Accountants at the relevant time, applied on a consistent basis (except for necessary or advisable changes in accordance with the promulgations of the Canadian Institute of Chartered Accountants). If and when Canadian GAAP does not address an accounting issue, then generally accepted accounting principles in the United States will apply.

1.9 "Improvement(s)"

means any modification, improvement, enhancement, variation, refinement, derivative or development relating to the ***Licensed Rights*** which

1.9.1 infringes any one or more claims of any of the ***Patents***; or

1.9.2 constitutes a technological advance of any degree using any of the ***Patents*** or ***Confidential Information*** (irrespective of whether it infringes one or more claims of the ***Patents***); and

1.9.3 was made and reduced into practice during the term of the ***License Agreement*** or within 12 (twelve) months of its termination or expiration by either ***Party***; and

1.9.4 when applicable, Canada is lawfully entitled to communicate and license to the Company without breaching any restrictions on use or disclosure to third parties.

1.10 "Intellectual Property"

means, as of the ***Execution Date***, all ***Patents***, trade-marks, copyrights, industrial designs, trade-names, trade secrets, ***Confidential Information*** and other intellectual property rights whether registered or not, whether proprietary or not

i) owned by or licensed to Canada, relating to the ***Licensed Rights***; or

ii) owned by or licensed to the Company, relating to the ***Improvements*** made by the Company, its ***Affiliates*** or sub-licensees,

as the case may be.

1.11 "License Agreement"

means this agreement and including all attached appendices and future amendments, and refers to the whole of this agreement, not to any particular section or portion thereof.

1.12 **"Licensed Product(s)"**

means any product resulting from ***Commercialization*** under this ***License Agreement***.

1.13 ***"Licensed Rights"***

means the exercise, as of the ***Execution Date***, in whole or in part, of

1.13.1 the ***Patents***; and

1.13.2 related ***Intellectual Property*** and ***Confidential Information*** and any subsequent changes thereto that are expressly incorporated into the ***License Agreement***,

within the ***Field of Use*** as listed in Appendix A (Description of the ***Licensed Rights***).

1.14 ***"Party"***

means any one of the signatories to the ***License Agreement*** and "***Parties***" means both of them.

1.15 ***"Patents"***

means

1.15.1 the patents and patent applications as listed in Appendix A (Description of the ***Licensed Rights***);

1.15.2 any author certificates, inventor certificates, utility certificates, improvement patents and models and certificates of addition, and includes any divisions, reissues, renewals, reexaminations and extensions thereof, and all continuations, continuations-in-part and divisionals of the applications for such patents, continuations, continuations-in-part, extensions, re-issues thereof for such patents, including, but not limited to, those patents listed in "Appendix A" and any subsequent patents whose priorities are derived from any patents listed in Appendix A; and

1.15.3 subsequently patented ***Improvements*** to ***Patents***.

1.16 ***"Sale"***

means without limitation the act of transferring (conditionally or unconditionally, permanently or temporarily) the results of the exercise of the ***Licensed Rights*** for consideration including but not limited to sale, lease, gift, barter, exchange or other

disposition for value. (For greater clarity any internal corporate use / consumption whatsoever of the ***Licensed Rights*** by the Company or an ***Affiliate*** or sublicensee shall be deemed a ***Sale*** at the ***Sales Price*** at the lime of the use / consumption or allocation for internal use / consumption, whichever is the earlier).

1.17 ***"Sales Price"***

means the aggregate gross price paid by an arm's length purchaser or lessee for any of the results of the exercise of the ***Licensed Rights*** sold or leased by the Company without deduction, rebate or pass throughs. If the gross price is less than the fair market value, then, for royalty calculation purposes, the gross price shall be the fair market value as set by Canada in its unfettered discretion.

1.18 ***"Taxes"***

means taxes (including, without limitation, sates taxes, goods & services taxes, value added taxes, however described), levies, imposts, deductions, charges, license and registration fees, assessments, withholdings / withholding taxes and duties imposed by any jurisdiction or authority (including stamp and transaction taxes and duties) together with any related interest, penalties, fines and expenses in connection with them.

1.19 ***"Territory"***

means the entire world, always subject to:

1.19.1 the United Nations Act, R.S.C. 1985, Chap. U-2:
1.19.2 the Export & Import Permits Act, R.S.C. 1985;
1.19.3 Chap. E-19, Special Economic Measures Act, S.C. 1992, Chap. 17;
1.19.4 Foreign Extra-Territorial Measures Act, R.S.C. 1985 c. F-29; and
1.19.5 any other pertinent Canadian statutory or regulatory strictures.

For greater clarity ***Territory*** means all countries and jurisdictions of the world.

1.20 ***"VHF"***

means viral hemorrhagic fevers.

2.0 GRANT & RESERVATIONS

2.1 Grant:

Subject to:

2.1.1 the definitions, terms and conditions of the ***License Agreement***,

2.1.2 the Company complying with and not being in breach of any of the provisions of the ***License Agreement***, and

2.1.3 any third party peremptory rights,

Canada hereby grants to the Company a personal, non-transferable, sole, revocable, royalty-bearing license for ***Commercialization***.

Nothing herein shall constitute in any manner whatsoever:

2.1.4 an assignment or other transfer of proprietary rights in the ***Licensed Rights*** to the Company; or

2.1.5 any authorization or permission beyond that expressly given in this ***License Agreement***.

2.2 Carve Out

Notwithstanding anything to the contrary in the ***License Agreement***, Canada retains from the ***License Agreement***, any and all absolute and unfettered rights necessary to do the following:

2.2.1 improve the ***Licensed Rights*** or ***Patents***;

2.2.2 to carry out educational activities;

2.2.3 to pursue research and development, directly or indirectly, related to the ***Licensed Rights*** or ***Patents*** with or without the Company, collaborators or sponsors, with all attendant rights of publication;

2.2.4 to make, have made, manufacture, use, license sell and distribute and to administer (directly or through health care providers) to Canadians products resulting from the exercise of the ***Licensed Rights***, the ***Patents*** and the ***Improvements*** in the event of a public health emergency pertaining or related to *VHF* in Canada, for the purpose of prevention or treatment of *VHF*, where:

2.2.4.2 the Company has not obtained regulatory approval of its product(s) under the Food and Drugs Act of Canada at the time the emergency is identified by Canada; or

2.2.4.3 the Company is not able to satisfy the demand for its approved product(s) in Canada at the time the emergency is identified by Canada;

2.2.5 to make, have made, manufacture, use and distribute and to administer to Canada's staff products resulting from the exercise of the ***Licensed Rights***, the ***Patents*** and the ***Improvements***, for the purpose of prevention and treatment of *VHF*, whether in or outside a public health emergency in Canada or abroad, and

2.2.6 to make, have made, manufacture, use, license, sell and distribute and to administer (directly or through health care providers) products resulting from the exercise of the ***Licensed Rights***, the ***Patents*** and the ***Improvements***, outside of

Canada, for compassionate care purposes for the prevention or treatment of *VHF*, where:

2.2.6.2 the Company has not obtained regulatory approval of its product(s) under the laws of the foreign country in question at the time the compassion care is identified by Canada; or

2.2.6.3 the Company is not able to satisfy the demand for its approved products) in the foreign country in question at the time the compassionate care is identified by Canada.

2.3 Non Compete by Canada

Subject to clause 2.2, Canada shall not commercially compete with the Company, or grant a license to any third party for commercial purposes, within the ***Field of Use*** concerning the ***Licensed Rights*** in the ***Territory***.

2.4 Sublicensing Permitted

The Company is permitted to sub-license ***Affiliates*** and non-affiliated or non-controlled parties, on the same terms and conditions of this ***License Agreement***. The Company has no right to encumber any contractual, legal or equitable rights the Company may have against any ***Affiliate*** or sub-licensee in favour of any financial institution or any third party whatsoever.

2.5 Sublicensing Conditions

Any sub-license or any amendment to any sub-license granted by the Company to ***Affiliates*** and non-affiliated or non-controlled parties, shall:

2.5.1 be royalty-bearing, revocable, without the right to sub-sub-license, except with the prior written consent of Canada, which consent shall not be unreasonably withheld;

2.5.2 carry a royalty rate no less than that prescribed in the ***License Agreement***;

2.5.3 be only within the ***Territory*** or any portion thereof;

2.5.4 be only within the ***Field of Use*** or a subset thereof;

2.5.5 be subject to the same obligations and restrictions as those required of the Company under the ***License Agreement***;

2.5.6 be copied to Canada immediately following execution; and

2.5.7 not be a *de facto* assignment.

For greater clarity, Canada shall receive from the ***Affiliates*** and sub-licensees not less than the same amount of consideration Canada would have received from the Company,

had the Company conducted the ***Commercialization*** rather than the ***Affiliates*** or sub-licensees. The Company shall ensure that any monies owing to Canada from the ***Affiliates*** or sub-licensees are paid to Canada when due, and shall be liable for any such monies irrespective of whether or not the ***Affiliate*** or sub-licensee paid the Company.

2.6 Sub-Licensee Consideration

In addition to the royalties payable by the ***Affiliates*** and sub-licensees to Canada as contemplated in paragraph 2.5 (Sub-licensing Conditions), the Company shall also pay to Canada [*] paid by the ***Affiliates*** and sub-licensees to the Company.

2.7 Termination

Termination of the ***License Agreement*** shall also terminate any subsisting sub-licenses, but any consideration due or owing to Canada shall be paid promptly thereafter, and any and all unsatisfied obligations and rights shall subsist until satisfied.

3.0 TERM

3.1 Term

This ***License Agreement*** shall commence on the ***Execution Date*** and shall continue in force until the expiry of the last to expire of the ***Patents*** included in the ***Licensed Rights***, subject to:

3.1.1 early termination as prescribed under Article 15.0 (Termination); and

3.1.2 condition subsequent in paragraph 4.1 (Business Plan).

4.0 EXPLOITATION OF LICENSED RIGHTS

4.1 Business Plan

The Company shall submit a business plan to Canada within thirty (30) days of the ***Execution Date***. Canada shall have the right to request amendments to the business plan in order to ensure maximum commercial return to the Company and Canada in accordance with this Article 4 (Exploitation of Licensed Rights). Once Canada has accepted the business plan, the plan is then Appendix C (Business Plan) and all the Company's representations and statements in the plan are incorporated into the ***License Agreement***.

4.2 Disclosure Requirements

The business plan shall provide sufficient detail to show how the Company plans to diligently research, develop and promote and make commercially reasonable efforts to ***Commercialize***. This business plan shall also disclose any

4.2.1 distribution and agency arrangements contemplated by the Company;

4.2.2 market studies pertinent to the ***Licensed Rights***;

4.2.3 pro forma financial statements of sufficient detail to allow a thorough financial analysis of the Company's assumptions, projected revenue streams and costs.

4.3 Continuing Disclosure

During the term of the ***License Agreement***, the Company shall promptly provide to Canada any amendments or updates to the business plan.

4.4 Inducement

The Company acknowledges that the business plan as orally presented to Canada in a pre-contractual setting, and subsequently manifested in the written format under paragraph 4.1, as accepted by Canada is the major inducement for Canada to enter into the ***License Agreement*** on the terms and conditions prescribed herein.

4.5 Breach

If the Company

4.5.1 commits a misrepresentation, omission, concealment or incorrect statement of a material fact in the negotiations leading to the ***License Agreement*** in general or leading to or in the business plan in particular; or

4.5.2 breaches any representations or statements in the business plan,

then such failure is a material breach of the ***License Agreement*** which provides Canada with the discretionary election either to:

4.5.3 rescind the ***License Agreement*** and seek damages; or

4.5.4 maintain the ***License Agreement*** and seek damages alone.

4.6 Commercially Reasonable Efforts to Commercialize

As an inducement to Canada to enter into the ***License Agreement***, during the term (or the renewal) of the ***License Agreement***, the Company shall:

4.6.1 use commercially reasonable efforts to ***Commercialize***;

4.6.2 use commercially reasonable efforts to create and satisfy demand for the ***Licensed Rights***; and

4.6.3 not do, or assist anyone to do, anything inimical to the ***Commercialization***.

Payment of fees and royalties under Article 5 (Fees & Royalties) does not relieve the Company of its obligation under paragraph 4.6 (Commercially Reasonable Efforts to Commercialize).

4.7 Shelving a Fundamental Breach

Any “parking”, “shelving” or other activity or inactivity concerning the ***Licensed Rights*** whereby the Company is not using its commercially reasonable efforts to diligently and aggressively ***Commercialize*** the ***Licensed Rights*** in the ***Territory***, is a fundamental breach of the ***License Agreement***.

4.8 Research Support Collaboration

In carrying out basic research and development activities concerning the ***Licensed Rights*** and *VHF* vaccine during the term of this ***License Agreement***, and any renewal thereof, the Company shall make good faith efforts to collaborate with Canada on [*] of such activities, under collaborative research agreements containing commercially reasonable terms and conditions as agreed to by the ***Parties*** at that time. Any payments made by the Company pursuant to such collaborations shall not diminish or affect the Company’s obligation to pay fees and royalties under Article 5 (Fee and Royalties).

5.0 FEES AND ROYALTIES

5.1 Fees

The Company shall pay to Canada the following non-refundable lump sums:

5.1.1 PATENT FEES
[*], payable within thirty (30) calendar days of the ***Execution Date***, as a reimbursement of ***Patent*** costs incurred by Canada to date;

5.1.2 SIGNING FEE
[*], payable upon signing, as a non-creditable and non-refundable signing fee in consideration of the execution of the ***License Agreement***;

5.1.3 MILESTONE FEES [*] lump sum payable on the earlier of [*] or [*] years of the *Execution Date*, whichever comes first;
5.1.4 MILESTONE FEES [*] lump sum payable on the earlier of [*] or [*] years of the *Execution Date*, whichever comes first;
5.1.5 MILESTONE FEES [*] lump sum payable on the earlier of [*]or [*] years of the *Execution Date*, whichever comes first;
5.1.6 MILEPOST FEES [*] lump sum payable on the earlier of [*] or [*] of the *Execution Date*, whichever comes first.

5.2 Royalty Percentage Rate

The Company shall pay to Canada a royalty rate of [*] of the ***Sales Price*** of ***Licensed Products*** sold by the Company, its ***Affiliate(s)*** or sublicensees.

5.2.1 The royalty rate shall be lowered to [*] if: a) an additional technology is required to ***Commercialize***; and b) the additional technology is actually licensed by the Company from a third party and the latter actually charges royalties to the

Company for such a license (as shown by documentation sufficient to establish the requirement and the actual license).

5.2.2 The rate shall be towered to [*] if: a) two (2) or more additional technologies are required to ***Commercialize***; and b) the additional technologies are actually licensed by the Company from one or more third parties and the latter actually charge royalties to the Company for such a license (as shown by documentation sufficient to establish the requirement and the actual license).

5.3 Minimum Royalty

Notwithstanding any other provision of the ***License Agreement***, the Company shall pay to Canada a minimum annual royalty of [*], payable on or before January during each year of the ***License Agreement***. Such amounts paid shall be creditable against royalties owed under clause 5.2 (Royalty Percentage Rate) and sub-license payments owed under clause 5.4 (Sub-Licensing Consideration) in the same year.

5.4 Sub-Licensing Consideration

The Company shall pay to Canada [*] paid by the ***Affiliates*** and the sublicensees to the Company. Such payments shall be over and above the royalty rate paragraph 5.2 (Royalty Percentage Rate) (whether or not such consideration was directly, indirectly or derivatively paid or provided) including without limitation any equity.

5.5 Sub-Licensee's Fees

5.5.1 COLLECTION AND ENFORCEMENT BY THE COMPANY

The Company shall ensure that royalties payable to Canada from ***Affiliates*** and sub-licensees shall be remitted directly to the Receiver General for Canada, at the address provided in Article 20.1 (Notice). The Company shall take any necessary actions (at the Company's own cost) to collect, enforce and remit royalties or other consideration owing to Canada by the ***Affiliates*** and sub-licensees.

5.5.2 SUB-LICENSEE'S ARREARS PAID BY THE COMPANY

If an ***Affiliate*** or sub-licensee has royalties or other consideration owing to Canada under a sub-license for a period in excess of thirty (30) days, then the Company shall pay to Canada that amount owing within the next fourteen (14) days immediately following the aforementioned thirty (30) days.

5.6 Taxes

The Company shall pay ***Taxes*** at the applicable prevailing rates exigible on the Company's activities under the ***License Agreement***, including without limitation ***Commercialization*** or on the payment of royalties, including any withholding taxes that in the first instance are levied against Canada

5.7 Payment to Canada

Unless the ***License Agreement*** expressly provides otherwise, the Company shall pay any and all monies and consideration owing to Canada as follows:

5.7.1 TIME & MODE

quarterly, by cheque or money order, commencing on December 31, 2010 and thereafter on March 31, June 30, September 30 and December 31 of each year of this ***License Agreement***;

5.7.2 CURRENCY & ADDRESS

except for royalties generated from ***Commercialization*** within Canada, cheques for the payment of royalties shall be in U.S. funds (at the conversion rate stated in the Wall Street Journal on the day prior to the date payment is due) and made payable to the "Receiver General for Canada". The cheque(s) shall be sent to

Director, Intellectual Property Management & Business Development Public Health Agency of Canada
1015 Arlington Street, Suite 2420
Winnipeg, Manitoba, Canada
R3E 3R2;

5.7.3 ACCOMPANYING DOCUMENTATION

each cheque shall be accompanied by a statement bearing the name / identification of this ***License Agreement*** and the ***Licensed Rights***, and showing the period covered, the total sales, per country sales, the per country royalty applicable and the total royalty paid or consideration paid, as applicable.

5.8 Payments to Canada after Termination

The Company shall pay to Canada any consideration due and payable under the ***License Agreement***, whether incurred before termination or after, in accordance with Article 15 (Termination).

5.9 Payment after Expiry of Patents

The Company shall continue paying the amounts as prescribed in this Article, notwithstanding any impeachment proceedings, or the expiry, expungement or other nullification of the ***Patents***.

5.10 No Set-off

Notwithstanding any other provision of the ***License Agreement***, any consideration payable to Canada by the Company under the ***License Agreement*** is unconditional and

non-cancelable. Further, the Company shall not have the right of set-off, deduct or counter-claim against any such consideration.

5.11 Accounting Approach

5.11.1 GAAP

The Company shall use GAAP in the calculation of consideration owing to Canada.

5.11.2 ACCRUAL

Royalties accrue on receipt of payment by the Company (or ***Affiliates*** or the sub-licensees) for the ***Licensed Rights***.

5.11.3 INTEREST OF OVERDUE ACCOUNTS

In the event the Company fails to make any payment under the ***License Agreement*** when due and payable, then interest on any unpaid amount shall accrue at a rate of four (4)% above the base rate of the Bank of Montreal, Toronto, from time to time in force during the period of non-payment.

5.11.4 OTHER BASIS FOR PAYMENTS

If the Company receives any lump sum or other payments, royalties (including royalty payments received from third parties), or any other income or consideration for, or in respect of the ***Commercialization*** of the ***Licensed Rights***, then the Company shall include such additional income in calculating the ***Sales Price***.

6.0 RECORDS AND AUDIT

6.1 Records Maintenance

The Company shall keep true and accurate records and maintain such records relating to ***Commercialization*** and all other obligations of the Company under the ***License Agreement*** during the term of the ***License Agreement*** and for ten (10) years following the termination or expiration of the ***License Agreement***.

6.2 Record Type

For greater clarity and without limiting the generality of the foregoing, records cited in paragraph 6.1 (Records) shall comprehensively address:

6.2.1 financial, business, manufacturing and technical support, including without limitation sales reports, inventory reports, subcontractor and distributor agreements, tax returns, catalogues, price lists, shipping records, invoice registers, invoices, financial statements and ledgers; and

6.2.2 quality standards and monitoring reports and records.

6.3 Records, Access to those held by Off Site Professionals

The Company irrevocably authorizes its independent accountants, KPMG LLP, to provide to Canada's independent accountants any information it may have with respect to the ***Commercialization.***

6.4 Audit Document Right

Upon the written request of Canada and with at least fifteen (15) calendar days prior notice, the Company shall permit an independent accountant, retained by Canada, to inspect all relevant records (whether held internally by the Company or at the offices of professional advisors or elsewhere) in order to ascertain the accuracy of such royalties, reports and ***Commercialization*** efforts. Such inspections shall be during business hours and in a manner that does not unduly disrupt the Company's business. The Company shall allow the accountant to make any necessary copies of the records that the independent accountant deems fit.

6.5 Audit Interview Right

In addition to the rights in paragraph 6.4, upon the written request of Canada, the Company shall allow the independent accountant to interview key personnel of the Company. The independent accountant, in its unfettered discretion, shall determine who the key personnel are for the purposes of the interview. The Company acknowledges that the independent accountant may have more than one interview with key personnel

6.6 Audit Confidentiality

The independent accountants retained by Canada shall inform Canada whether the Company has complied with its obligations under the ***License Agreement***, including without limitation whether all royalties and consideration due and payable were paid as prescribed to Canada and marketing efforts and any inaccuracies in such payments. Subject to the information contained in the foregoing audit reports, the independent accountants shall neither reveal to Canada any of the Company's internal documentation or records, nor disclose any notes or copies of the Company's records made by the independent accountants, excluding anything necessary for the report.

6.7 Duration

The auditing and verification provisions herein shall continue for 10 years following the expiry or termination of this ***License Agreement***.

6.8 No Waiver

Any royalty payment or report accepted by Canada shall not constitute a waiver by or estoppel against Canada concerning the contractual right to audit the Company, and Canada shall continue to have the right to audit as prescribed in the ***License Agreement***.

Furthermore, an audit shall not preclude Canada from conducting subsequent audit or audits.

6.9 Discrepancy Percentage

With respect to the earned royalties (paragraph 5.2, Royalty Rate, paragraph 5.4. Sub-License Fees) in the event of any discrepancy uncovered by the audit, in excess of five percent (5.0%) of the amounts paid during the audited period, the Company shall pay forthwith to Canada both the discrepancy and the cost of the audit. Overpayments shall be credited against the next payment due by the Company to Canada.

6.10 Breach of Records Audit Article Material

The record and audit requirements are a material term of the ***License Agreement***.

7.0 REPORTS & QUALITY CONTROL

7.1 Report - Commercialization & Marketing

The Company shall, on or before the 45th day following each calendar quarter, during the term hereof and any renewal, submit to Canada written reports as to the Company's activities with respect to the exercise of ***Licensed Rights*** during the preceding twelve (12) months. Such reports shall contain:

7.1.1 a description of the steps taken by the Company to develop and ***Commercialize*** and sub-license;

7.1.2 a description of the marketing conditions for the products or processes created by the exercise of the ***Licensed Rights***; and

7.1.3 a report an the production, use and sales of the products or processes created by the exercise of the ***Licensed Rights***.

7.2 Report - Officer's Certificate

The report from the Company shall also contain a certificate from either the CEO or CFO of the Company attesting to the fact that the Company has been using commercially reasonable efforts to develop and ***Commercialize*** the products or processes created by the exercise of the ***Licensed Rights*** and that ***Commercialization*** is a material and active element of the Company's business.

7.3 Report - Audited Statement 8 Remittances

In addition to the requirements of paragraphs 7.1 (Report Contents General) and paragraph 7.2 (Report - Officer's Certificate), the report from the Company to Canada shall also contain an audited statement, which includes, without limitation:

7.3.1 an audited statement, including the amount of the products or processes created by the exercise of ***Licensed Rights*** sold by the Company and the amount of royalties or other consideration payable;

7.3.2 the names and addresses of all ***Affiliates*** and sub-licensees to whom the ***Licensed Rights*** has been sub-licensed;

7.3.3 a full account of all revenues generated by such ***Affiliates*** and sub-licenses, including the amount of products or processes created by the exercise of ***Licensed Rights*** sold;

7.3.4 a calculation of the amount due to Canada for the royalties and consideration as stipulated herein as required under paragraphs 2.5 (Sublicensing Conditions) and paragraph 2.6 (Sub-licensee Consideration); and

7.3.5 subject to paragraph 5.7 (Payment to Canada) any remittances then payable to Canada, payable to the Receiver General for Canada, of the amount of royalties or other consideration so payable.

7.4 Report— Quality Control

In addition to the foregoing, the report shall also contain internal audit results, conducted quarterly, showing the quality standards of the products or processes created by the exercise of the ***Licensed Rights*** at all production sites and at the major sale or distribution sites.

7.5 Quality Control Obligations

The Company shall comply with all quality requirements for the products or processes created by the exercise of the ***Licensed Rights*** that are prescribed by:

7.5.1 Canada from time to time in writing; and

7.5.2 any regulatory or statutory authority.

7.6 Quality Control Spot Audits by Canada

The Company shall allow Canada to conduct spot audits of the Company production and sales sites during operating hours anywhere in the ***Territory*** to ensure compliance with the prescribed quality standards.

7.7 Quality Control Spot Audits on behalf of Canada

Canada may ask the Company to conduct spot audits of the Company production and sales sites anywhere in the ***Territory*** and to disclose those results to Canada within 15 days of each audit.

7.8 Annual Report

The Company shall, on or before the 31st day of May of each calendar year, during the term hereof and any renewal, submit to Canada a copy of:

7.8.1 the Company's certified financial statements and evidence of renewal of the Company's insurance policy under section 13 of the License Agreement;
7.8.2 the Company's annual reports to shareholders; and
7.8.3 material revisions to the Company's business plan.

7.9 Annual Face-To-Face Meeting

The Company shall, on the 121st day of each calendar year, during the term of the ***License Agreement*** and any renewal, meet face-to-face with Canada to provide a progress report on the activities carried out by the Company under the ***License Agreement***.

7.10 Material terms

The reporting and quality requirements and audit rights are a material term of the ***License Agreement***.

8.0 OWNERSHIP OF TECHNOLOGY / IMPROVEMENTS

8.1 Canada Owns Licensed Rights

The Company agrees and is estopped from alleging otherwise that:

8.1.1 the ***Licensed Rights*** are vested in and are the sole property of Canada;

8.1.2 ownership and all rights related to, connected with, or arising out of the foregoing, including, without limitation:

8.1.2.2 ***Patents, Intellectual Property, Confidential Information***, copyright, the right to produce, publish or cause to be produced, and all published information material and documents;

8.1.2.3 the right to issue a license;

are vested in and are the sole property of Canada, and

8.1.3 the Company shall have no rights to the foregoing except as may be expressly granted under this ***License Agreement***, and the Company shall not apply for any proprietary or other right and shall not divulge or disclose, without the prior written consent of Canada, any information, material or documents concerning the foregoing or make available in any way or use the ***Licensed Rights***, except as expressly provided in the ***License Agreement***.

8.2 No Impeachment

The Company shall neither impeach, contest or otherwise attack, directly or indirectly, the validity, enforceability or ownership of the ***Patents*** or any ***Intellectual Property*** rights held by Canada, or Canada's right, title and interest in and to the ***Licensed Rights*** nor assist, counsel or procure any third party to do the same.

8.3 Inimical Use of Confidential Information

The Company shall not use any ***Confidential Information*** obtained from Canada in the negotiation of the ***License Agreement***, under due diligence searches or otherwise related to this ***License Agreement***, in any manner that either violates the Company's rights and obligations under the ***License Agreement*** or is inimical to the interests of Canada.

8.4 Improvements - Ownership

Unless expressly agreed to otherwise in writing by the ***Parties***, the ownership of any ***Improvement*** made by or on behalf of a ***Party*** shall immediately, after creation, vest exclusively in that ***Party***.

8.5 Company Improvements - Disclosure

The Company shall disclose to Canada forthwith all ***Improvements***, innovations and discoveries developed or created by or on behalf of the Company, solely or jointly with others (including ***Affiliates*** and sub-licensees), which related to the ***Licensed Rights***, together with any ***Intellectual Property*** rights residing therein.

8.6 Company Improvements — License to Canada

The Company hereby grants to Canada a personal, non-transferable, non-exclusive, worldwide, perpetual, irrevocable, royalty-free and fully paid-up license for the ***Improvements*** (including data and reports related thereto), made by or on behalf of the Company under paragraph 8.4 (Improvements — Ownership) and disclosed to Canada under paragraph 8.5 (improvements — Disclosure) for the purposes set out in paragraph 2.2 (Carve Out). Further, Canada may sub-license such ***Improvements*** for the purposes of carrying out the purposes set out in paragraph 2.2 (Carve Out).

Termination of the ***License Agreement*** shall not terminate the foregoing license to Canada or any subsisting sub-licenses.

9.0 DISCLAIMERS

9.1 Estoppel Statement/Disclaimer of Express / Implied Warranties

The Company acknowledges that there is some question as to the integrity of ownership of the ***Licensed Rights*** and ***Patents*** and the Company accepts those risks.

The ***Licensed Rights*** and ***Patents*** are provided to the Company on an "as is" basis. Canada makes no warranties, representations or conditions, express or implied, of any nature, and Canada disclaims all warranties, representations or conditions, for the ***Licensed Rights***, the ***Patents***, the ***Intellectual Property*** or the ***Confidential Information*** including, without limitation:

9.1.1 merchantability;
9.1.2 quality (either as discussed or with respect to a sample / model);
9.1.3 fitness for any or a particular purpose:
9.1.4 commercial utility or practical purpose;
9.1.5 susceptibility of yielding valuable results or results are free of defects or otherwise harmless;
9.1.6 latent or other defects;
9.1.7 infringement or non-infringement of Patents or other third party rights;
9.1.8 conformity with the laws of any jurisdictions; or
9.1.9 fitness for the Company's corporate objectives (whether or not expressly or implicitly communicated to Canada).

For greater certainty, no information or advice given by Canada shall create a warranty or representation or condition other than as expressly stated in the ***License Agreement***. The Company hereby accepts the ***Licensed Rights*** and the ***Patents*** "as is", with all faults, and the entire risk as to satisfactory quality, performance, accuracy and effort is with the Company. In no event shall Canada be liable for any direct, indirect, incidental, special, exemplary, or consequential damages (including, but not limited to, procurement of substitute goods or services, loss of use, data or profits, or business interruption) however caused and on any theory of liability, whether in contract, strict liability, or tort (including negligence or otherwise) arising in any way out of the exercise of the ***Licensed Rights*** by the Company, its ***Affiliates*** or sub-licensees, even if advised of the possibility of such damage.

9.2 Disclaimer of Statutorily Implied Warranties

No legal or equitable warranties or conditions implied by law or convention under any domestic, foreign or international legal regime, or from a course of dealing or usage of trade, shall apply to the ***License Agreement***. The Company acknowledges this disclaimer and is estopped from relying on any such representations, warranties or conditions against Canada.

9.3 Confidential Information Without Warranty / No Reliance

The Company shall not rely in any way on the quality, accuracy or completeness of any ***Confidential Information*** provided by Canada under the ***License Agreement***. Any use of such ***Confidential Information*** shall be at the Company's sole risk and expense. Any ***Confidential Information*** provided to the Company by Canada is without any warranty or guarantee or representation or warranty of any kind whatsoever other than as expressly provided herein.

9.4 No Liability to Canada from Exercise of Rights

The Company undertakes to use the ***Licensed Rights*** and apply ***Confidential Information*** of Canada entirely at its own risk and under its own responsibility, and that the Company will have no recourse against Canada with respect to any consequences of such application.

9.5 Third Party Representations

The Company shall not represent to any ***Affiliate*** or sub-licensee the existence of any warranty or condition concerning the ***Licensed Rights***.

9.6 Disclosure & Due Diligence

The Company acknowledges that:

9.6.1 Canada has made full and frank disclosure of all facts the Company deemed relevant before executing the ***License Agreement***;

9.6.2 The Company has conducted a due diligence search of all matters relevant to the ***Licensed Rights***, the ***Patents*** and the ***License Agreement***;

9.6.3 Canada has made all best efforts to identify the significant characteristics of the ***Licensed Rights*** and that Canada makes no representation that all the characteristics both favorable and unfavorable have been identified; and

9.6.4 Canada is either under no duty to warn the Company or the Company unconditionally waives any such duty, about the ***Licensed Rights*** or ***Commercialization***.

10.0 PATENT PROTECTION & REGULATORY REQUIREMENTS

10.1 Patent Costs

The Company shall pay all costs related to and maintaining ***Patents*** (and shall reimburse Canada for any of these costs that Canada may pay during any term of the ***License Agreement***), as they are incurred, and within thirty (30) days of being invoiced for such costs.

10.2 Right to Patent

Nothing in the ***License Agreement*** shall limit or restrict Canada from seeking to patent ***Improvements*** made by Canada.

10.3 The Company Shall Obtain Regulatory Permissions

The Company shall use commercially reasonable efforts to obtain any authorizations, permits, certificates or other regulatory permissions which may be required in order for the Company to legally carry out all of its activities under the ***License Agreement***,

including but not limited to ***Commercialization***, at the Company's sole cost and expense without right of set-off.

10.4 Her Majesty Not Obligated

Nothing in the ***License Agreement*** shall obligate any emanation of Her Majesty the Queen in Right of Canada to grant any required authorizations, permits, certificates or other regulatory permissions. Conversely, there is no implication by the execution of the ***License Agreement*** that the Company will be granted any required authorization, permits, certificates or other regulatory permissions necessary for the effective Commercialization of the ***Licensed Rights***.

11.0 CONFIDENTIALITY / FIDUCIARY OBLIGATIONS & EQUITABLE REMEDIES

11.1 Existing Confidentiality Agreements

The ***Confidentiality Agreements*** entered into by the Parties on May 1, 2007, and November 1, 2008, respectively, shall end on the ***Execution Date*** of the ***License Agreement***. However, all rights and obligations of the Parties under the ***Confidentiality Agreements*** that expressly or by their nature survive termination of those agreements shall continue in full force and effect until they expressly or by their nature expire.

11.2 Confidentiality Obligations

Commencing on the ***Execution Date*** of this ***License Agreement***, ***Confidential Information*** disclosed by one ***Party*** to the other ***Party*** under this ***License Agreement*** shall be:

11.2.1 held in confidence and in trust by the receiving ***Party***;

11.2.2 used by the receiving ***Party*** exclusively for the purposes authorized under the ***License Agreement*** and for no other purpose whatsoever;

11.2.3 safeguarded by the receiving ***Party*** using all reasonable measures and taking such action as may be appropriate to prevent the unauthorized access, use or disclosure of the ***Confidential Information***; and

11.2.4 not disclosed to third parties without the prior written consent of the disclosing ***Party***.

11.3 No Waiver of Privilege

Each ***Party*** acknowledges that the ***Confidential Information*** of the disclosing ***Party*** is the property of the disclosing ***Party*** or a third party and that none of the latter intend to or do waive any rights, title or privilege they may have in respect of any of the ***Confidential Information***.

11.4 Common Law Duty of Confidentiality

Nothing in this ***License Agreement*** derogates, displaces or otherwise diminishes the common law or equitable duty of confidentiality vested in the receiving ***Party*** concerning the ***Confidential Information***.

11.5 Confidentiality Exclusions

Article 11.2 (Confidentiality Obligations) does not apply to information which, even if it may be marked “confidential’, is not really confidential, in that

11.5.1 IN PUBLIC DOMAIN - the information was legally and legitimately in the public domain through no act or omission of the receiving ***Party*** at the time of disclosure by the receiving ***Party***;

11.5.2 PUBLISHED - the information was legally and legitimately published or otherwise becomes part of the public domain through no act or omission of the receiving ***Party*** at the time of disclosure by the receiving ***Party***;

11.5.3 ALREADY KNOWN TO THE RECEIVING PARTY - the information was already in the possession of the receiving ***Party*** at the time of disclosure and was not acquired by the receiving ***Party***, directly or indirectly, from the disclosing ***Party*** (as shown by documentation sufficient to establish the timing of such possession), and the receiving ***Party*** is free to disclose the information to others without breaching any contractual or trust obligations or common law duties;

11.5.4 THIRD PARTY DISCLOSES - the information becomes available from an outside source who has a lawful and legitimate right to disclose the information to others, and the receiving ***Party*** is free to disclose the information to others without breaching any contractual or trust obligations or common law duties;

11.5.5 INDEPENDENTLY DEVELOPED - the information was independently developed by the receiving ***Party*** without any of the ***Confidential Information*** being reviewed or accessed by the receiving ***Party*** (as shown by documentation sufficient to establish the timing of such development); or

11.5.6 JUDICIAL/ADMINISTRATIVE ORDER - the information was released due to a compulsory order under a judicial process or under a compulsory regulatory (including securities) requirement, none of which was invited by, or consented to, by the receiving ***Party*** and the receiving ***Party*** made all reasonable efforts to secure a court order to limit production, use and disclosure of the information to the narrowest class practical under the circumstances.

11.6 Secure Location

Each ***Party*** shall keep the ***Confidential Information*** of the other ***Party*** in a secure location accessible only to its employees specifically authorized to have access pursuant to this ***License Agreement***. Each ***Party*** shall ensure that its employees complies with the

terms and conditions of this ***License Agreement*** and shall enter into agreements with such employees if necessary to give effect to this obligation.

11.7 Return of Confidential Information

If this ***License Agreement*** expires or is terminated, the ***Parties*** shall return to each other the ***Confidential Information*** disclosed to them under this ***License Agreement*** and any notes, reports and other materials prepared by the receiving ***Party*** from the disclosing ***Party***’s ***Confidential Information*** except that Canada shall be entitled to retain one copy of such records for the purposes of meeting Canada’s obligations under the federal laws of Canada and for the purposes of paragraph 8.6 (Improvements - License to Canada).

11.8 Confidential Information is Proprietary

The ***Confidential Information*** of each ***Party*** is and shall remain the exclusive property of that ***Party*** or third parties and the receiving ***Party*** shall not claim any rights, title, interest or ownership in the ***Confidential Information***. The receiving ***Party*** shall not contest any such rights, title, interest or ownership.

11.9 Legal and Equitable Remedies

Should a ***Party*** commit or threaten to commit a serious or material breach of its confidentiality or fiduciary obligations under this Article 11, then the other ***Party*** may pursue any and alt legal and equitable remedies, including without limitation, injunctive relief, accounting for profits, redistribution, damages, constructive trust and disgorgement. Disgorgement means, for the purposes of the ***License Agreement***, the ejection of all benefits gained by the receiving ***Party***, traceable to the material breach, notwithstanding that such disgorgement may exceed the damages directly suffered by the disclosing ***Party*** or deprivation suffered by the disclosing ***Party*** for such breach.

11.10 No Hiring of Canada's Employees

The Company shall not:

11.10.1 solicit, hire, retain or secure;

11.10.2 directly or indirectly, including without limitation, the use of consultants, ***Affiliates*** or third parties;

11.10.3 any of the agents, servants or employees of Canada;

11.10.4 which agents, servants or employees are employed or retained in connection with, or whose responsibilities relate in whole or in part, to the ***Confidential Information***, the ***Licensed Rights*** or the ***Patents***; or helped produce or create the ***Confidential Information***, the ***Licensed Rights*** or the ***Patents***;

to accept employment with the Company of any of its ***Affiliates***, unless

11.10.5 Canada grants in advance its written permission to such a solicitation or the employment of such a person; or

11.10.6 [*] have elapsed from the ***Execution Date***.

11.11 Exemption

The prohibition in paragraph 11.10 (No Hiring of Canada's Employees) does not apply to general solicitations of employment issued by the Company and any hiring resulting from such solicitations that are:

11.11.1 not directed towards the employees of Canada; and

11.11.2 do not involve the ***Confidential Information***, the ***Licensed Rights*** or the ***Patents***.

11.12 Contact Only Under License Agreement

The ***Parties*** shall have no discussions, correspondence or other contact with the other ***Party***, its licensees, confidants or any person concerning the ***License Agreement***, except through the designated representative of the other ***Party*** or any delegates identified in writing by the designated representative from time to time.

11.13 Terms Of Agreement Confidential But Not Existence of Agreement

The ***Parties*** agree that terms of this ***License Agreement*** are confidential but not its existence. The terms of this ***License Agreement*** shall not be disclosed by a Party unless disclosure is required by law or if the other ***Party*** agrees to the disclosure in writing prior to disclosure.

12.0 CORPORATE REPRESENTATIONS & WARRANTIES

12.1 The Company Incorporated & Authorized 8 Bound

The Company represents and warrants to Canada that as of the ***Execution Date***:

12.1.1 ABILITY

it can ***Commercialize***, and the Company has or will have the necessary access to funds, resources, knowledge, facilities and personnel to perform its obligations under the ***License Agreement***, including to use commercially reasonable efforts to ***Commercialize***;

12.1.2 AUTHORIZATION

it is authorized and has the corporate power and authority to negotiate, execute, comply with and satisfy its obligations, without qualification, under the ***License Agreement***;

12.1.3 INCORPORATION JURISDICTION

it has been duly incorporated and organized under the laws of the state of Delaware and is validly existing under the laws of Iowa;

12.1.4 EXTRA-PROVINCIAL REGISTRATION

it is duly qualified, licensed or registered to carry on business in the Province or State of Delaware.

12.1.5 ENFORCEABLE

it is bound by the ***License Agreement***, upon execution, and the ***License Agreement*** constitutes a legal, valid and binding obligation on the Company, enforceable against the Company in accordance with the terms of the ***License Agreement***, except as those terms may be limited by applicable bankruptcy laws and general principles of equity,

12.1.6 LITIGATION

it has no knowledge of any legal proceeding or order pending against or, to the knowledge of the Company, threatened against or affecting, the Company or any of its properties or otherwise that could adversely affect or restrict the ability of the Company to consummate fully the transactions contemplated by this ***License Agreement*** (including without limitation the ***Commercialization***) or that in any manner draws into question the validity of this ***License Agreement***;

12.1.7 VERACITY OF STATEMENTS

no representation or warranty by the Company contained in this ***License Agreement*** and no statement contained in any certificate, schedule or other instrument furnished to Canada pursuant hereto or in connection with the transactions contemplated hereby, contains any untrue statement of a material fact or omits to state a material fact;

12.1.8 INCONSISTENT AGREEMENTS / OBLIGATIONS

it has not given any understanding, express or implied, to any third party which would:

12.1.8.2 preclude the Company from fulfilling its obligations under the ***License Agreement***; or

12.1.8.3 cause the Company to breach an agreement with a third party;

12.1.9 NO MARCH IN RIGHTS

it is not subject any “march in” or third party rights, (contractual or statutory, contingent or vested) which would give that third party any rights to the ***Licensed Rights*** not otherwise explicitly described in the ***License Agreement***; and

12.1.10 NO BREACH OF THIRD PARTY AGREEMENTS

its execution of the ***License Agreement*** does not contravene its constituent documents or any law, regulation or official directive or any of its obligations or undertakings by which it or any of its assets are bound or cause a limitation on its powers or the powers of its directors to be exceeded.

12.2 Canada Authorized

Canada represents and warrants to the Company as of the ***Execution Date***:

12.2.1 AUTHORIZATION

Canada has the power and authority to negotiate, execute and comply with the ***License Agreement***, subject to all applicable laws and the royal prerogative; and

12.2.1.2 no further action is required by or in respect of any governmental or regulatory authority; and

12.2.1.3 the ***License Agreement*** is legal, binding and enforceable in accordance with its terms.

13.0 INDEMNITY, INSURANCE AND LIABILITY ALLOCATION & CAPS

13.1 The Company’s Indemnification

The Company shall;

13.1.1 indemnify; and

13.1.2 save harmless;

Canada (and her employees, servants and agents),

13.1.3 from and against all claims, demands, losses, penalties, damages, costs, (including reasonable solicitor and own-client costs and expert witness costs), actions, suits or other proceedings whatsoever, whether groundless or otherwise,

13.1.4 brought or prosecuted in any manner which heretofore or hereafter may be made by a third party against Canada or her employees, servants and agents;

13.1.5 however and whenever arising out of, relating to, occasioned by or attributed to,

a) any acts or conduct (including, without limitation, omissions, misrepresentations, errors and offences) of the Company, its employees, servants, agents, advisors, sub-licensees or ***Affiliates*** (whether by reason of negligence or otherwise) in the performance by the Company of the provisions of the ***License Agreement*** or any activity undertaken or purported to be undertaken under the authority or pursuant to the terms of the ***License Agreement***, including without limitation, exercise of the ***Licensed Rights*** and ***Commercialization***;

b) any infringement or alleged infringement by the ***Patents***, the ***Licensed Rights*** or ***Licensed Products*** of proprietary rights of any including, without limitation, patent, trade-mark, copyright or trade secret rights;

c) any claim the ***Patents***, the ***Licensed Rights*** or the ***Licensed Products*** or any aspect or use thereof by the Company infringes or constitutes misappropriation of the intellectual property rights of any third party; and

d) any claim or demand against the ***Patents***, the ***Licensed Rights***, the ***Licensed Products*** or the interest of Canada or the Company therein.

Further, the Company shall not third party Canada for any such claims, actions, suits or other proceedings taken solely against the Company and the Company hereby expressly waives any rights it has against Canada for claims of infringement.

13.2 Indemnity Separate / Continuing

The foregoing indemnity is a continuing obligation, separate and independent from the other obligations of the Company and survives termination of, expiration of, or the acceptance of repudiation of the ***License Agreement***. It is not necessary for Canada to incur expense or make payment before enforcing a right of indemnity conferred hereunder.

13.3 Insurance

The Company shall ensure that both the Company and each of its ***Affiliates*** and sub-licensees shall obtain and maintain, throughout the term of the ***License Agreement*** (and any renewal thereof) or duration of the sub-licenses (as the case may be), comprehensive general liability insurance for any and all claims, actions, liabilities and expenses resulting from the ***Commercialization*** of the ***License Rights***.

13.3.1 INSURANCE COMPANY

The insurance policy shall be obtained from a qualified insurance company licensed to do business in the applicable jurisdictions.

13.3.2 NAMED INSURED

The insurance policy shall name Her Majesty the Queen in Right of Canada and Her employees, servants and agents as “additional insureds”.

13.3.3 LIMITS

As of the ***Execution Date***, the insurance policy shall include commercial general liability insurance, and shall have monetary limits in the amount not less than one million dollars ($1,000,000) for each single occurrence or claim. Following the submission of an Investigational New Drug covering a Licensed Product and prior to the beginning of a Phase 1 Clinical Study, the insurance policy shall include commercial general liability insurance, that includes products liability insurance, and shall have monetary limits in an amount not less than five million dollars ($5,000,000) for each single occurrence or claim. The minimum amount of insurance coverage required under this ***License Agreement*** shall not be construed as a limit of liability.

13.3.4 TERMINATION NOTICE

The insurance policy shall provide for thirty (30) business days written notice by the insurer to the Company and Canada by registered or certified mail in the event of any modification, cancellation or termination of the insurance policy.

13.3.5 COPY

The Company shall provide Canada a copy of the insurance policy not later than 30 days alter execution of the ***License Agreement***, and thereafter upon the written request of Canada. This obligation shall apply each time the monetary limits are increased pursuant to clause 13.3.3, in which case the copy shall be provided not later than 30 days after the monetary limits in the insurance policy are increased. This obligation shall survive termination or expiration of the ***License Agreement***.

13.3.6 INSURANCE UNAVAILABLE

If insurance required to meet the monetary limits in clause 13.3.3 is unavailable, the ***Parties*** shall review the situation, and Canada may elect to either allow the Company to obtain the insurance that is available, or alternatively terminate the ***License Agreement***.

13.4 Canada’s Liability Cap

Canada’s liability for:

13.4.1 breach of the representations, conditions or warranties contained herein or any of the other provisions of the ***License Agreement*** or any other breach giving rise to liability, including a breach of a condition or fundamental term or fundamental breach or breaches; or

13.4.2 in any other way arising out of or related to the ***License Agreement***; or

13.4.3 for any cause of action whatsoever and regardless of the form of action (including breach of contract, trust, strict liability, tort [*], or any other legal or equitable theory);

shall be limited to the Company's actual direct (immediate and foreseeable at the time of negotiation to both ***Parties***), provable damages in an amount not to exceed in the aggregate a sum equal to or less than the net consideration received by Canada from the Company under paragraph 5.2 (Royalty Percentage Rate) for the time period commencing from the ***Execution Date*** up to and including the date of judicial judgment or arbitrator's decision.

13.5 Excluded Heads of Damage

Canada shall not be liable to the Company, its employees, servants, agents, successors, assigns, ***Affiliates*** or sub-licensees for damages in respect of:

13.5.1 incidental, indirect, special, punitive, exemplary damages;

13.5.2 any economic loss, consequential damages, relational loss, including but not limited to lost business revenue, lost profits, business interruption, failure to realize expected savings, loss of data, loss of business opportunity suffered by the Company or any claim whatsoever and whenever made against the Company by any other party;

(whether grounded in tort [*], strict liability, contract, trust or otherwise,) even if:

13.5.3 Canada was advised of the possibility of such damages, or

13.5.4 the damages encompassed by subparagraphs 13.5.1 and 13.5.2 were foreseeable by Canada, or

13.5.5 such damages resulted from a fundamental breach of the ***License Agreement***.

Further, Canada shall have no duty to warn the Company for matters arising directly or indirectly under the ***License Agreement***.

13.6 No Actions Against Employees

The Company acknowledges and estopped from and waives any rights the Company might have to commence and prosecute any action whatsoever, regardless of form or grounds (including without limitation negligence, misrepresentation, fiduciary, deceit) against any of Canada's employees, servants, agents or officers, arising out of any

13.6.1 claimed breach of the ***License Agreement***;
13.6.2 transactions under the ***License Agreement***;
13.6.3 negotiations leading to the ***License Agreement***; or
13.6.4 in any other way related to the ***License Agreement***.

For greater clarity, the Company's remedies for any breach of or ***Dispute*** under the ***License Agreement***, lies only against Canada, and only within the aforementioned parameters prescribed by the ***License Agreement***.

13.7 Notifications

Canada shall notify the Company of any claim that falls within the parameters of the respective indemnification obligations as soon as practical. In any case such notice shall be made forthwith upon notice that a claim may be prosecuted or a cause of action exists.

14.0 INFRINGEMENT

14.1 Third Party Suit

Subject to Article 13 (Indemnification), in the event of any threatened or actual suit against the Company in consequence of the exercise of any rights and licenses granted herein, the Company shall; promptly inform Canada and the ***Parties*** will Jointly decide on the steps to be taken in the circumstances. In any event, the Company will always have the sole right to defend itself as it determines against any suit or other action brought against the Company or its employees or agents.

14.2 Infringement Uncovered

Each ***Party*** will notify the other promptly in writing when any infringement of the ***Licensed Rights*** or ***Patents*** is uncovered or suspected.

14.3 Company May Sue

The Company shall have the right to enforce the ***Patents*** against any infringement or alleged infringement thereof, and shall at all times keep Canada informed as to the status thereof. Subject to Canada's prior written approval (which will not be unreasonably withheld), the Company may, at its own expense, institute suit against any such infringer or alleged infringer and prosecute such suit in a manner consistent with the terms and provisions hereof. Canada shall reasonably cooperate in any such litigation at the Company's expense, and the Company shall keep Canada apprised in a timely manner of all litigation activities. In any litigation under this article, the Company shall not have the right to settle or otherwise compromise Canada's position as a licensor or owner of the ***Patents*** without Canada's prior written consent.

14.4 Distribution of Company's Recovery

In the event of a recovery by the Company of punitive and non-punitive damages (net of legal fees and out of pocket costs of the action) under paragraph 14.3 for royalty-bearing products, the Company shall pay to Canada [*] of such recovery.

14.5 Canada May Sue

If the Company elects not to enforce the ***Patents*** as to any infringement or alleged infringement thereof, then the Company shall so notify Canada in writing within one (1) month of receiving notice that an infringement exists, and Canada may, in its sole judgment and at its own expense, take steps to enforce the ***Patents*** against such infringement or alleged infringement and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover for its own account any damages, awards or settlements resulting therefrom.

15.0 TERMINATION

15.1 By Canada for Cause

The ***License Agreement***, at the option of Canada, without prejudice to any other rights in law of equity held by Canada (including any right of indemnity), may be terminated forthwith by Canada without compensation to the Company if:

15.1.1 INSUFFICIENT EFFORTS

The Company fails to use its commercially reasonable efforts to develop or ***Commercialize*** and does not cure such failure within ninety (90) days of written notice from Canada;

15.1.2 NO PAYMENT

The Company fails to make any payment owed to Canada under the ***License Agreement*** and does not make such payment within sixty (60) days of the due date;

15.1.3 BREACH OF CONFIDENTIALITY

The Company uses or discloses ***Confidential Information*** of Canada in a manner inconsistent with its obligations under the ***License Agreement*** or fails to safeguard the ***Confidential Information*** of Canada;

15.1.4 BREACH OF BUSINESS PLAN

The Company fails, neglects, refuses or is unable to comply with the business plan created and submitted under paragraph 4.1 (Business Plan);

15.1.5 QUALITY CONTROL & AUDIT

The Company refuses, neglects or fails to meet quality standards or allow access for quality audit purposes contrary to paragraph 7.0 (Reports & Quality Control) or provide or allow the audit of the reports and records as required under Article 6.0 (Records and Audit);

15.1.6 CEASES BUSINESS

The Company ceases to actively carry on business;

15.1.7 MULTIPLE BREACHES

The Company breaches three or more provisions of the ***License Agreement*** within any consecutive twelve (12) month period, notwithstanding that such breaches were subsequently cured;

15.1.8 CROSS-DEFAULT

The Company breached a provision of another agreement with Canada that was executed with the Public Health Agency of Canada, and that breach occurred during the term of the ***License Agreement***;

15.1.9 CRIMINAL CONVICTION

The Company was convicted of a criminal or regulatory offence, the nature of which directly or indirectly affects the ability of the Company to conduct itself hereunder or to ***Commercialize*** in an effective and timely manner, or otherwise prejudices ***Commercialization***;

15.1.10 GENERAL BREACH

The Company commits or permits a breach of any of the other terms and conditions herein contained and does not remedy such breach within sixty (60) days after being required in writing to do so by Canada;

15.1.11 REPUDIATES

The Company expressly or implicitly repudiates the ***License Agreement*** by refusing or threatening to refuse to comply with any of the provisions of the ***License Agreement***.

15.2 Automatic Termination

The ***License Agreement*** and all rights granted to the Company pursuant to the ***License Agreement*** shall immediately terminate and revert to Canada by operation of contract, without prejudice to any other rights in law of equity held by Canada (including any right of indemnity) and without compensation to the Company, effective the business day prior to the applicable triggering event, namely if:

15.2.1 ASSIGNMENT

The Company assigns the ***License Agreement*** without the prior written consent of Canada, contrary to the provisions of paragraph 18.2 (No Assignment Without Consent); or

15.2.2 BANKRUPTCY

The Company becomes bankrupt or insolvent or otherwise

15.2.2.2 has a receiving or winding up order made or sought against it;

15.2.2.3 has a meeting proposed or convened, seeking or actually passing a resolution to appoint a trustee or official manager;

15.2.2.4 has a receiver, receiver-manager, liquidator, trustee in bankruptcy, custodian or any other officer with similar powers appointed for the Company or such an order is sought;

15.2.2.5 has any or all of its assets seized or otherwise attached for the benefit of creditors;

15.2.2.6 proposes or convenes a meeting to seek or passes a resolution for winding up;

15.2.2.7 takes the benefit of any statute, at the time in force, relating to bankrupt or insolvent debtors for the orderly payment of debts;

15.2.2.8 makes a general assignment for the benefit of creditors;

15.2.2.9 submits a proposal or arrangement under any debtor/creditor legislation;

15.2.2.10 is the subject of a petition or files an assignment under the Bankruptcy Act or any successor legislation; or

15.2.2.11 does or attempts anything analogous to the aforementioned events or having a substantially similar effect to any of the aforementioned events under the laws of any jurisdiction.

15.3 Termination Not A Penalty

The Company acknowledges, and is estopped from alleging otherwise, that the termination provisions in paragraph 15.2 do not constitute a penalty, and are otherwise fair, just and proportional given:

15.3.1 the nature of the ***Parties***;
15.3.2 their respective mandates and corporate objectives;
15.3.3 the allocation of risks under the ***License Agreement***;
15.3.4 the goals of the ***Parties***;
15.3.5 nature of the ***Licensed Rights***; and
15.3.6 the consequences to Canada if the Company commits the aforementioned breaches.

15.4 Procedure

Termination shall be implemented by a notice effective as of the date slated therein, but termination shall be subject to paragraph 15.6 (The Company’s Duties on Termination) and be without prejudice:

15.4.1 to the right of Canada to sue for and recover any royalties or other sums due Canada; and

15.4.2 to the remedy of either ***Party*** in respect of any previous breach of the ***License Agreement***.

15.5 Effect on Sub-licensees

All sub-licenses, including those granted to ***Affiliates***, shall terminate with the ***License Agreement***.

15.6 The Company's Duties on Termination or Expiration

A) Upon termination of the ***License Agreement*** by Canada, the Company shall at its own cost:

15.6.1 return immediately to Canada all ***Licensed Rights*** and ***Confidential Information*** of Canada, including copies thereof;

15.6.2 certify in writing to Canada within thirty (30) days of termination, that to the best of the Company's knowledge, all of the ***Confidential Information*** (including copies) of Canada has been returned;

15.6.3 deliver a detailed statement to Canada of the inventory of the products made from the exercise of the ***Licensed Rights*** then existing, but not sold by the Company, as of the date of expiration or termination;

15.6.4 provide Canada the right of first refusal to purchase from the Company any products made from the exercise of the ***Licensed Rights*** inventory at fair market value;

15.6.5 dispose of any remaining products made from the exercise of the ***Licensed Rights*** in inventory as specified by Canada subject always to any obligations under Article 5.0 (Fees & Royalties);

15.6.6 pay all costs due under the ***License Agreement*** either by the Company on its behalf or a sub-licensee, up to and including the termination date, within thirty (30) days of the termination;

15.6.7 pay all costs due under the ***License Agreement***, subsequent to the termination, for any products made from the exercise of the ***Licensed Rights*** sold after termination, within thirty (30) days of the liability being incurred;

15.6.8 grant back to Canada any technology rights, clinical or research data arising from the ***Licensed Rights*** or otherwise under the ***License Agreement***;

15.6.9 assign to Canada (or her nominee) any equities, goodwill, or other rights which the Company has or alleges to have acquired in the ***Licensed Rights*** or derived in the ***Commercialization***. The Company shall also execute such further documentation as Canada may reasonably request m order to confirm such assignment;

15.6.10 pay immediately to Canada any royalties, fees, reimbursements or other financial obligations irrespective of the fact such monies are owed, but for the termination or expiration, not yet payable; and

15.6.11 assign or transfer for [*] in total consideration, any and all authorizations, permits, certificates or other regulatory permissions obtained in order to Commercialize, to any third party identified by Canada or to Canada itself, within ninety (90) days of termination or expiration, unless otherwise requested by Canada.

B) Upon expiration of the ***License Agreement***, the Company shall at its own cost, perform the duties set out in sections 15.6.1 to 15.6.8. Further, upon expiration, the Company shall grant to Canada the right to exercise an option to negotiate with the Company an agreement dealing with the matters set out in sections 15.6.9 to 15.6.11. The ***Parties*** shall negotiate the agreement in good faith. The agreement shall contain mutually acceptable terms and conditions and the consideration shall be commercially reasonable.

15.7 Surviving Obligations

All obligations of the ***Parties*** which expressly or by their nature survive termination or expiration, shall continue in full force and effect subsequent to and notwithstanding such termination or expiration, until they are satisfied or by their nature expire. For greater clarity, and without restricting the generality of the foregoing, the following provisions survive termination or expiration:

15.7.1 Paragraph 2.2 (Carve Out);
15.7.2 Article 5.0 (Fees and Royalties);
15.7.3 Article 6.0 (Records & Audit);
15.7.4 Paragraphs 8.4 to 8.6 (Improvements — Ownership, Company Improvements -Disclosure, Company Improvements - License to Canada);
15.7.5 Article 11.0 (Confidentiality / Fiduciary & Equitable Remedies);
15.7.6 Article 13.0 (Indemnity, Insurance and Liability Allocation & Caps); and
15.7.7 Paragraph 15.6 (The Company's Duties on Termination or Expiration).

16.0 ALTERNATE DISPUTE RESOLUTION (ADR)

16.1 Negotiations

16.1.1 INFORMAL NEGOTIATIONS

If a ***Dispute*** arises between the ***Parties***, then: within 6 months from when the allegedly aggrieved ***Party*** knows or should know of the ***Dispute***, the contact individuals in Article 20.1 (Notice) shall,

16.1.1.2 contact their counterpart, and attempt bona fide efforts to diligently resolve the ***Dispute*** through amicable negotiations:

16.1.1.3 provide full, frank and timely disclosure of all relevant facts, information and documents to facilitate those negotiations;

16.1.1.4 resolve the ***Dispute*** within 7 days;

16.1.1.5 reduce the ***Dispute*** to writing, and if the contact persons cannot agree on the wording of the ***Dispute***, both contact persons shall submit to each other their written version of the ***Dispute***.

16.1.2 FORMAL NEGOTIATIONS

If the ***Parties*** are unable to resolve the ***Dispute*** within fourteen (14) calendar days from the receipt by the other ***Party*** of the written version of the ***Dispute***, then within the following thirty (30) days the Dispute shall be referred to the Chief Public Health Officer, on behalf of Canada, and to the CEO, on behalf of the Company (or their directly reporting designates), to negotiate a resolution.

16.1.2.2 These individuals may not delegate, substitute or direct, surrogates for them at these negotiations.

16.1.2.3 These individuals shall meet in person to negotiate and the ***Parties*** shall bear their own costs.

16.1.2.4 Unless otherwise agreed, the meetings shall alternate between Company, HQ, and Canada, HO, commencing in Ottawa, Ontario, for the first meeting for the first ***Dispute***. There shall be one meeting only per ***Dispute***, which meeting shall not exceed one (1) business day in length.

16.1.2.5 The ***Parties*** may bring no more than two consultants to a meeting. The two consultants shall not have a right of audience or otherwise to negotiate the ***Dispute***.

16.2 Mediation

If, within thirty (30) days following the close of the meeting under paragraph 16.1.2 (Formal Negotiations), the ***Parties*** have not succeeded in negotiating a resolution, then the ***Parties*** shall jointly submit the ***Dispute*** to mediation.

16.3 Skip Mediation - Direct to Arbitration

If the ***Parties*** cannot agree to jointly submit the ***Dispute*** to mediation, then either ***Party*** may submit the ***Dispute*** to binding arbitration.

16.4 Mediation Process

The Parties shall

16.4.1 APPOINTMENT OF MEDIATOR

appoint a mutually acceptable mediator with sixty (60) days from the close of the formal negotiation meeting under sub-paragraph 16.1.2 (Formal Negotiations);

16.4.2 GOOD FAITH EFFORTS

participate in good faith in the mediation and negotiations related thereto;

16.4.3 EMPOWERED REPRESENTATIVES

representatives sent to the mediation shall be empowered or have sufficient delegated authority to resolve, compromise, negotiate or settle the ***Dispute*** submitted to mediation, without seeking further instructions or approvals from any superiors or committees / corporate structures, unless the nature, seriousness or financial quantum of the ***Dispute*** by law or corporate policies or practices requires approval from the respective corporate or government structure. In such event, such approval shall be obtained within five (5) business days of the proffer of any settlement offer;

16.4.4 COSTS

bear the costs of the mediation equally, except that each ***Party*** shall bear its own personal costs of the mediation;

16.4.5 FULL DISCLOSURE

a full, frank and timely manner all relevant facts, information and documents to facilitate the mediation; and

16.4.6 LOCATION

The mediation shall take place in the city that was not the site of the formal negotiations for the ***Dispute***.

16.5 Unsuccessful Mediation —Remit to Arbitration

The ***Dispute*** shall be referred to binding arbitration by either or both ***Parties*** if the ***Parties*** are not successful in resolving the ***Dispute*** through mediation.

16.6 Arbitration - Structure

After negotiation and if applicable, mediation), any subsisting ***Dispute*** between the ***Parties***, shall be referred to arbitration by a written submission signed by either Canada or the Company.

16.6.1 FORUM LAWS PROCEDURAL RULES

The arbitration tribunal shall be governed by the UN Commercial Arbitration Code, referred to in the Commercial Arbitration Act, R.S.C. 1985, c.C-34.6 ("Code").

16.6.2 NUMBER OF ARBITRATORS

The arbitration tribunal shall consist of one arbitrator chosen by the ***Parties***.

16.6.3 ISSUE BEFORE ARBITRATOR

The scope of the arbitration shall be limited to the resolution of the ***Dispute*** submitted to arbitration.

16.6.4 APPLICABLE SUBSTANTIVE LAW

The arbitration tribunal shall decide the ***Dispute*** (including limitations, set-off claims) in accordance with the laws in force in the Province of Ontario and any applicable federal laws.

16.6.5 NO EQUITY

The arbitration tribunal shall not be authorized to decide *ex aequo et bono* or as *amiable compositeur*.

16.6.6 ARBITRAL INTERIM ORDERS

Subject to subparagraph 16.6.5 (No Equity) the arbitration tribunal shall have all the powers of a court at law or in equity, including the power to make interim orders, orders of injunction (either mandatory or prohibitory), rectification, expungement and orders for interest. However in no case will the final decision breach the strictures of subparagraph 16.6.5 (No Equity).

16.6.7 LOCATION

The proceedings shall take place in the city that was not the site of the mediation (or if there was no mediation, in the city that was not the site of the negotiation meeting), unless the ***Parties*** agree otherwise.

16.6.8 LANGUAGE

The language used in the proceedings shall be English.

16.6.9 NOTICES

All written communication shall be delivered to the ***Parties*** hereto in the manner provided for in Article 20.1 (Notice).

16.6.10 COSTS

The costs of the tribunal's fees and expenses shall be shared equally by the ***Parties***. The ***Parties*** shall bear their own costs except that the losing ***Party*** shall pay all costs, fees, levies and ***Taxes*** arising from and necessitated by the enforcement of the arbitration tribunal's award, including, without limitation, registration enforcement charges or other judicial levies.

16.7 Emergencies / Judicial Jurisdiction

The ***Parties*** are not precluded from bringing an application to a Court having jurisdiction for interim or interlocutory relief, in law or in equity, including, without limitation, injunctive relief, if such relief is urgently required to preserve the rights or property of either or both of the ***Parties***, pending the final determination of those rights in a subsequent arbitral proceeding as contemplated in this Article.

16.8 Final & Binding

Subject to the Code, the ***Parties*** hereto agree that the award and determination of the arbitration tribunal shall be:

16.8.1 final and binding on both ***Parties***;

16.8.2 without right of appeal;

16.8.3 the exclusive remedy between the ***Parties***, regarding any claims, counterclaims, issues or accountings presented or pled to the arbitration tribunal, and

the judgment upon the award rendered by the arbitration tribunal may be entered in any Court having jurisdiction thereof or having jurisdiction over either of the ***Parties***.

16.9 Arbitral Decision Deadline

The arbitration tribunal retainer shall contain the obligation that the arbitration tribunal render a written decision with reasons within thirty (30) days from the close of the hearing or submission of written argument.

16.9.1 If the facts and law are either too complicated or voluminous to allow a properly considered decision within thirty (30) days, then the decision shall be rendered in not less than one hundred and eighty (180) days, but the arbitrator shall notify the

Parties of the longer decision period by not later than the close of final arguments.

16.10 Power to Settle

The ***Parties'*** representatives at any arbitration throughout the arbitration shall be empowered or have sufficient delegated authority to resolve, compromise, negotiate or settle the ***Dispute*** submitted to arbitration, without seeking further instructions or approvals from any superiors or committees / corporate structures. The representatives shall either be the same persons as in paragraph 16.1.2 (Formal Negotiations) or their immediate subordinates.

16.10.1 Notwithstanding the foregoing, if the nature, seriousness or financial quantum of the ***Dispute*** in law or corporate policies/practices requires approval from the Board of Directors, or the Chief Public Health Officer, as the case may be, then, such approval shall be obtained within five (5) business days of the proffer of any settlement offer.

16.10.2 If applicable, the arbitration tribunal shall withhold its final decision until the ***Parties*** have ceased negotiating a settlement.

16.11 Adjournment to Empower Representative

Breach of paragraph 16.10 (Power to Settle, [Duly empowered representative]), shall entitle the other ***Party*** to seek an adjournment of the arbitration proceedings, to give the breaching ***Party*** time to appoint a duly empowered representative within the thirty (30) days. All costs directly traceable to such delay, including arbitration tribunal costs and the non-breaching ***Party's*** costs, shall be paid forthwith by the breaching ***Party***.

16.12 Deemed Abandonment

Failure of the breaching ***Party*** to appoint such a representative within the thirty (30) day period shall be deemed a withdrawal or abandonment of the ***Dispute*** by the breaching ***Party*** and the arbitrator shall render a formal decision, finding in favour of the non-breaching ***Party***.

16.13 General ADR Conditions

16.13.1 NO LITIGATION

If either ***Party*** has submitted the ***Dispute*** to court, which ***Dispute*** should properly have been submitted for resolution by arbitration, then the court filing ***Party*** shall discontinue the court proceedings forthwith, upon notice from the other ***Party***, and both ***Parties*** shall remit the ***Dispute*** to arbitration hereunder.

16.13.2 OBLIGATIONS DURING ALTERNATE DISPUTE RESOLUTION (ADR)

During the progress of ADR, the ***Parties*** hereto shall continue to diligently perform their obligations under the ***License Agreement***.

16.13.3 PRIVILEGE

Neither ***Party*** shall be required to disclose documents that are privileged or created in contemplation of litigation. If a ***Party*** does disclose such a document during ADR, that disclosure shall not be construed as a waiver of any privilege unless the disclosing ***Party*** so elects in writing.

16.13.4 CONFIDENTIALITY

The ***Parties*** shall keep confidential the existence of the proceeding under this article, and any element of the ADR (including, without limitation, all conduct, statements, promises, offers, views, pleadings, briefs, documents, testimonies, identity of witnesses, submissions, awards and opinions, whether oral or written), made in the course of the ADR, except as may be lawfully required in judicial or regulatory proceedings relating to the arbitration or otherwise. Without limiting the generality of the foregoing, and for

greater clarity, neither ***Party*** may make any publicly accessible statements / publications nor any shareholder or press announcements concerning any element of the ADR beyond the fact of the ADR.

16.13.5 ADR DISCLOSURES NOT ADMISSIBLE IN SUBSEQUENT PROCEEDINGS

Subject to subparagraph 16.13.6 (Normally Admissible Evidence), all conduct, statements, promises, offers, views and opinions, whether oral or written, made in the course of the ADR by either ***Party***, or the mediator or arbitrator, are not discoverable or admissible for any purposes, including impeachment, in any subsequent litigation or other proceedings involving the ***Parties***.

16.13.6 NORMALLY ADMISSIBLE EVIDENCE

Evidence that would otherwise be discoverable or admissible and was not created for an ADR, is not excluded from discovery or admission solely as a result of its use in the ADR.

16.14 Limitation

All ***Disputes*** must be submitted to ADR within one (1) year from the time of the facts giving rise to the ***Dispute***. Failure to submit the ***Dispute*** within the one (1) year period means a loss of all rights to submit the ***Dispute*** to ADR or litigation.

16.15 Material Breach

The failure, neglect or unwillingness of a ***Party*** to use or diligently participate in and prosecute a ***Dispute*** through ADR is a material breach of the ***License Agreement***.

17.0 INTENT AND INTERPRETATION

17.1 Entire Agreement

The ***License Agreement*** constitutes the entire and exclusive agreement between the ***Parties*** pertaining to the ***Commercialization*** and licensing and supersedes all prior agreements, conditions, obligations, understandings, and negotiations both written and oral. The ***License Agreement*** sets forth all obligations, undertakings, conditions, representations and warranties forming part of, or in any way affecting or relating to the ***Commercialization***. The ***Parties*** acknowledge that with respect to the ***Commercialization*** there are no agreements, obligations, undertakings, representations or warranties whether collateral, oral or written, between the Company and Canada other than those expressly set out in the ***License Agreement***.

17.2 No Third Parties

Neither the ***License Agreement*** or any provision thereof is intended to confer upon any person other than the ***Parties***, any rights or remedies hereunder.

17.3 No Pre-Contractual Inducing Representations

The ***License Agreement*** supersedes and revokes all negotiations, arrangements, letters of intent, offers, proposals, brochures, term sheets, representations, memoranda of understandings and information conveyed, whether oral or in writing or electronically, between the ***Parties***, or any other person purporting to represent the Company or Canada. Each of the ***Parties*** agrees that:

17.3.1 neither has been induced to enter into the ***License Agreement*** by any representations whatsoever not set expressly forth in the ***License Agreement***;

17.3.2 neither has relied on any such representations;

17.3.3 no such representations shall be used in the interpretation or construction of the ***License Agreement***; and

17.3.4 no claims (including, without limitation, loss of profits, indirect, incidental, consequential damages and economic loss) arising directly or indirectly, from any such representation, negligent or otherwise, shall accrue in law or equity, or be pursued by the Company, and Canada shall have no liability for any such claims.

17.4 Due Diligence Search

The Company agrees that it has conducted its own due diligence examinations in order to satisfy itself of the full, true and plain disclosure of all facts pertinent to the ***Licensed Rights*** and all representations made by Canada.

17.5 Independent Legal Advice

It is acknowledged by the ***Parties*** that each has had legal advice to the full extent deemed necessary by each ***Party***. Furthermore, the ***Parties*** acknowledge that neither acted under any duress in negotiating, drafting and executing the ***License Agreement***.

17.6 No Adverse Presumption in Case of Ambiguity

There shall be no presumption that any ambiguity in the ***License Agreement*** be resolved in favour of either of the ***Parties***. For greater certainty, the *contra proferentum* rule shall not be applied in any interpretation of the ***License Agreement***.

17.7 Severability

If a jurisdiction declares, finds or holds any part of the ***License Agreement*** invalid, void, unenforceable or contrary to public policy for any other reason, then:

17.7.1 NON-MATERIAL

if the invalid provision is not material or fundamental to the ***License Agreement***, the invalid provision shall not affect the validity of the remainder which remainder shall continue if full force and effect and be construed as if the ***License Agreement*** had been executed without the invalid provision in that jurisdiction only;

17.7.2 MATERIAL

if the invalid provision is material to the ***License Agreement*** then that provision shall be "read down" or replaced with a provision which accomplishes, to such extent as is possible, the original legal and business purpose of such provision in a valid and enforceable manner, in that jurisdiction and the remainder of the ***License Agreement*** shall remain binding on the ***Parties***; and

17.7.3 FUNDAMENTAL

if the invalid provision is fundamental to the ***License Agreement***, including any of the elements of a bare license, then:

17.7.3.2 the jurisdiction which found the invalidity shall be deleted from the ***Territory***; or

17.7.3.3 if the jurisdiction cannot be deleted from the ***Territory***, or there is more than one jurisdiction, then the ***License Agreement*** shall terminate.

17.8 Successors and Assigns

The ***License Agreement*** will be for the benefit of and be binding upon the heirs, executors, administrators, permitted successors, permitted assigns, and permitted ***Affiliates*** of the Company and other legal representatives, as the case may be, of each of the ***Parties***. Every reference in the ***License Agreement*** to any ***Party*** includes the heirs, executors, permitted administrators, permitted successors, permitted assigns, and ***Affiliates*** and other permitted legal representatives of the ***Party***.

17.9 Plurality and Gender

Reference to a ***Party*** will be read as if all required changes in the singular and plural and all grammatical changes rendered necessary by gender had been made.

17.10 Not a Joint Venture

The *Parties* expressly disclaim any intention to create a partnership, joint venture or joint enterprise. The ***Parties*** acknowledge and agree that:

17.10.1 nothing contained in the ***License Agreement*** nor any acts of any ***Party*** shall constitute or be deemed to constitute the ***Parties*** as partners, joint venturers or principal and agent in any way or for any purpose;

17.10.2 no ***Party*** has the authority to act for, or to assume any obligation or responsibility on behalf of any other ***Party***; and

17.10.3 the relationship between the ***Parties*** is that of licensor and licencee.

17.11 Minister Not Fettered

Nothing in the ***License Agreement*** shall derogate or otherwise fetter the ability of Canada to regulate, administer, manage or otherwise deal with public health and all attendant matters thereto.

17.12 Federal Legislation

The application to the ***License Agreement*** of any Federal act or regulation includes any subsequent amendment, revision, substitution, consolidation to that act or regulation, notwithstanding that such amendment, revision or substitution occurred after the execution of the ***License Agreement*** or may have a retroactive effect.

17.13 Right to Legislate

Nothing in the ***License Agreement*** shall prohibit, restrict or affect the right or power of the Parliament of Canada to enact any laws whatsoever with respect to any area of law

for which the Parliament of Canada has legislative jurisdiction, even if the enactment of any such law affects the ***License Agreement***, its interpretation, or the rights, obligations, liabilities, vested or not, accrued or accruing, of the ***Parties***.

17.14 Compliance with Law

The ***Parties*** shall comply with all applicable laws, as those laws may be amended, revised, consolidated, substituted, from time to time, even if such amendment, revision, consolidation, substitution derogates prospectively or retroactivity from the ***Parties'*** vested or accrued rights, obligations and liabilities under the ***License Agreement***.

17.15 No Implied Obligations

No implied terms or obligations of any kind, by or on behalf of either of the ***Parties***, shall arise from anything in the ***License Agreement***. The express covenants and agreements herein contained and made by the ***Parties*** are the only covenants and agreements upon which any rights against either of the ***Parties*** may be founded.

17.16 Access to Information

Notwithstanding any provision to the contrary in the ***License Agreement***, the Company acknowledges that Canada is subject to the Access to Information Act, R.S.C. 1985, c.A-1 and related acts, and may be required to release, in whole or in part, the ***License Agreement*** and any other information or documents in Canada's possession or control relating to the ***License Agreement*** and the ***Parties***.

17.17 Forum Conveniens & Applicable Laws

Subject to Article 16 (ADR) any ***Dispute***, shall be governed firstly by applicable Canadian Federal laws, and secondly by the laws of the Province of Ontario.
The ***Parties*** expressly exclude from the ***License Agreement***:

17.17.1 application of the United Nations Convention on Contracts for the International Sale of Goods;
17.17.2 International Sales of Goods Act; and
17.17.3 any conflict of laws, venue, forum non-conveniens, rules or principles which might refer ***Disputes*** to the laws of another jurisdiction.

17.18 Attornment

The ***License Agreement*** shall be governed by and construed in accordance with the laws in force in the Province of Ontario, Canada and shall be treated in all respect as an Ontario, Canada contract. Subject to Article 16 (Alternate ***Dispute*** Resolution (ADR)) the ***Parties*** irrevocably and unconditionally attorn to and submit to the exclusive jurisdiction of the courts of Ontario, Canada and all courts competent to hear appeals therefrom with respect to any ***Dispute*** now or hereinafter arising under the ***License Agreement***. The Parties waive any right each may have to object to an action being

brought in those courts including, without limitation, by claiming that the action has been brought in an inconvenient forum or that those courts do not have jurisdiction.

17.19 USA Jury Trial

If the ***License Agreement*** or any aspect of it becomes a subject of judicial proceedings whether in contract, tort, equity or otherwise, in the United States of America despite the ADR article and Forum Conveniens (paragraph 17.17), then the Company irrevocably waives any and all rights it has to a trial by jury in the United States. The Company agrees and consents that due to the technical and legal nature, including cross jurisdictional issues of the ***License Agreement*** or any aspect thereof, any such proceedings will be heard before a judge sitting alone.

17.20 USA Jury Trial / Treble Damages Addendum

For greater clarity, the Company waives any right to a trial by jury of any claim, demand action or caution of action

17.20.1 arising under the ***License Agreement***; or
17.20.2 in any way connect with or related or incidental to the dealings of the ***Parties*** in respect of the ***License Agreement*** or any other agreements or the transactions related hereto or thereto in each case whether now existing or hereafter;
17.20.3 whether in contract, tort, equity or otherwise.

The Company agrees and consents that any such claim, demand, action or cause of action shall be decided by a court without a jury. Canada may file an original counterpart of the ***License Agreement*** with the court as written evidence of the consent of the ***Parties*** to the waiver of their right to a trial by jury. In addition, the Company irrevocably waives any rights to triple/treble damages or punitive damages under U.S. or any other law.

17.21 Waiver of Counterclaims

The Company waives any and all of its rights to interpose any claims, deductions, setoffs or counterclaims of any nature in any ***Dispute*** with respect to the ***License Agreement***.

17.22 Due Diligence Audits

If in a subsequent transaction a third ***Party*** requires to review this ***License Agreement*** as part of a due diligence chain of title search, the Company hereby authorizes the release of this ***License Agreement*** subject to deleting any financial or proprietary or other ***Confidential Information*** contained herein.

17.23 Recitals Accurate

The ***Parties*** acknowledge the truth and accuracy of the recitals and further acknowledge that the recitals may be used by a court, mediator or arbitrator to help resolve any ***Dispute***.

17.24 Force Majeure

17.24.1 EVENTS

Subject to making all payments required under the ***License Agreement***, neither ***Party*** shall be in breach of any of its obligations under the ***License Agreement*** where the failure to perform or delay in performing any obligation is due, wholly or in part, directly or indirectly to the occurrence of a force majeure event including, without limitation:

17.24.1.2 war, whether declared or not, civil war, revolution, acts of piracy / terrorism, acts of sabotage;
17.24.1.3 natural disasters such as violent or destructive storms, cyclones, earthquakes, tidal waves floods, destruction by lightning;
17.24.1.4 explosions, fires, destruction of machines, factories, and any kind of installation;
17.24.1.5 boycotts, strikes and lock-outs of all kinds, go-slows, occupation of factories and premises, and work stoppages which occur in the enterprise of the ***Party*** seeking relief;
17.24.1.6 acts of governmental bodies, agencies, boards, whether lawful or unlawful other than those of the Public Health Agency of Canada,

but does not include:

17.24.1.7 the lack of regulatory or other approvals, licenses, permits and authorizations necessary for the performance of the ***License Agreement*** which are issued by a public authority of any kind whatsoever for which the Company did not apply for or diligently prosecute;
17.24.1.8 the inability of the affected ***Party*** to obtain financing or any other financial inability on the part of either ***Party*** to meet its obligations under the ***License Agreement***;
17.24.1.9 force majeure events that the affected ***Party*** knew or should have reasonably known at the time of negotiating the ***License Agreement*** were probable or avoidable or the effects of which could be minimized, and the affected ***Party*** took no steps to deal with such force majeure events, including without limitation obtaining the appropriate insurance, using updated machinery;
17.24.1.10 the portion of the breach or delay due to the failure of the affected ***Party*** to take all necessary reasonable steps to minimize, overcome or control the effects of the force majeure event.

17.24.2 DUTY TO NOTIFY

The ***Party*** affected by a force majeure event as contemplated in subparagraph 17.24.1 (Force Majeure) shall:

17.24.2.2 give notice to the other ***Party*** of such force majeure and its effects on the affected ***Party***'s ability to perform as soon as practicable after the force majeure and its effects upon the affected ***Party***'s ability to perform become known to that ***Party***. Notice shall be given when the ground of relief ceases;

17.24.2.3 take all reasonable efforts to correct, compensate or minimize the effect of the force majeure event.

17.24.3 COMMENCEMENT OF RELIEF

The affected ***Party*** shall in the affected jurisdiction only:

17.24.3.2 be excused of its obligations under the ***License Agreement*** to the extent necessitated by the force majeure event from the time of the force majeure event or if notice was not given as soon as practical, from the receipt of such notice. Failure to give notice makes the failing ***Party*** liable in damages for losses suffered by the other ***Party*** which otherwise could have been avoided; and

17.24.3.3 complete or continue performance of its obligations and duties under the ***License Agreement*** as soon as practical after the cessation, removal, or overcoming of the force majeure event.

17.24.4 TERMINATION OF AGREEMENT

If the force majeure event continues in excess of sixty (60) consecutive days, or in the aggregate 60 days over any consecutive 200 days, then at any time thereafter Canada shall have the option to renegotiate the ***License Agreement*** with the Company reasonably and in good faith. If the ***Parties*** are unable to agree to the terms of the proposed amended ***License Agreement*** within 60 days from the notice to negotiate, then the ***License Agreement*** may be terminated by Canada on the 61st day.

17.24.5 POSTPONEMENT OF OBLIGATIONS

Any obligations of a ***Party*** under the ***License Agreement*** shall be postponed automatically to the extent and for the period and only within the jurisdiction or jurisdictions that the affected ***Party*** is prevented from meeting those obligations by reason of any cause beyond its reasonable control (other than lack of funds and applicable regulatory approval). The affected ***Party*** shall immediately notify the other ***Party*** of the commencement, nature of such cause and probable consequence. The affected ***Party*** shall also use its

reasonable best efforts to render performance in a timely manner, utilizing all resources reasonably required in the circumstances.

17.25 Waiver

No condoning, excusing, or overlooking by either of the ***Parties*** of any default by the other ***Party***, at any time or times, in performing or observing any of the ***Parties'*** respective covenants, will operate as a waiver renunciation, surrender, of or otherwise affect the rights of the ***Parties*** in respect of any continuing or subsequent default. No waiver of these rights will be inferred from anything done or omitted by the ***Parties***, except by an express waiver in writing.

17.26 No Estoppel Due to Third Party Practices

No custom, practice or usage regarding other ***License Agreements*** between Canada and other ***Parties*** shall preclude at any time the strict enforcement of the ***License Agreement*** by Canada or the Company.

17.27 Contract Always Speaks

Where a matter or thing is expressed in the present tense, it shall be applied to the circumstances as they arise, so that effect may be given to the ***License Agreement*** according to its true spirit, intent and meaning.

17.28 Time is of the Essence

Time is of the essence in the ***License Agreement*** with respect to the financial and ***Commercialization*** obligations of the Company.

17.29 Headings

17.29.1 All headings in the ***License Agreement*** have been inserted as a matter of convenience and for reference only, and in no way define, limit, enlarge, modify, the scope or meaning of the ***License Agreement*** or any of its provisions.

17.29.2 Nevertheless an arbitrator or Judge may use any or all of the table of contents, recitals, and headings when reviewing the covenants, statements, representations & warranties and conditions subsequent to better understand the commercial and legal intent of the ***License Agreement's*** provisions.

17.30 Internal References

Any reference in the ***License Agreement*** to an Article, paragraph, sub-paragraph, will mean an Article, paragraph or sub-paragraph of the ***License Agreement***, unless otherwise expressly provided.

17.31 Precedence Over Appendices

If there is a conflict or ambiguity between the ***License Agreement*** proper and any appendix thereto, the interpretation consistent with ***License Agreement*** proper (taking into consideration the statements in the recitals and headings) shall prevail and apply, notwithstanding any wording to the contrary in the applicable appendix.

17.32 Appendices

Subject to paragraph 17.31 (Precedent Over Appendices) the documents attached hereto as Appendix A, B, C and D form an integral part of this ***License Agreement*** as fully as if they were set forth herein *in extenso*, and consist of:

Appendix "A" — DESCRIPTION OF THE LICENSED RIGHTS
Appendix "B" — CONFIDENTIALITY AGREEMENTS
Appendix "C" — BUSINESS PLAN
Appendix "D" — AFFILIATES

18.0 LEGAL RIGHTS

18.1 Amendments

No modification or waiver of any provision of the ***License Agreement*** will be inferred from anything done or omitted by either of the ***Parties***, except by an express amendment in writing, duly executed by the ***Parties*** in advance.

18.2 No Assignment Without Consent

The ***License Agreement*** is personal to the Company. The Company shall not assign the ***License Agreement*** or any of the Company's rights, duties or obligations under the ***License Agreement*** to a third party without the prior written consent of Canada, such consent not to be unreasonably withheld. Any attempt to assign this ***License Agreement*** or any of the Company's rights, duties or obligations under the ***License Agreement*** without the prior written consent of Canada is void.

18.3 Mode of Assignment / Approval Conditions

Without derogating from paragraph 18.2 (Assignment), the Company shall not assign (or transfer, sell, encumber, pledge, grant a security interest sub-license or otherwise deal) or permit any such assignment, in whole or in part, of the ***License Agreement*** or any of its interest, rights or obligations hereunder, whether such assignment takes place by way of:

18.3.1 sale of assets;

18.3.2 sale of shares;

18.3.3 amalgamation, merger or other reorganization of the Company;

18.3.4 merger, transfer, conversion, assignment, redemption, issuance, sale, cancellation, pledge, conversion or other dealings with any securities of the Company;

18.3.5 operation of law;

18.3.6 acquisition by a person or persons acting in concert of a majority interest of the securities of the Company by a person or persons acting in concert who did not hold such a majority interest at the time of the initial public offering (IPO) or at any time after the IPO.

18.3.7 operation of contract; or

18.3.8 otherwise in any manner or structure whatsoever;

without the prior written consent of Canada, which consent subject to subparagraph 18.3.9 will not be unreasonably withheld.

18.3.9 Any consent from Canada shall be contingent and effective only upon receipt by Canada of payment of [*].

18.3.10 Consent to any assignment will not be construed as consent to any other assignment.

18.4 No Consent — Material Breach

Failure of the Company to obtain the prior written consent of Canada to any assignment shall be deemed to be a material breach of the ***License Agreement***.

18.5 Assignment Prejudicial - Compensation

It will not be unreasonable for Canada to refuse to consent to any assignment if it is foreseeable that the assignment might negatively affect Canada in any way, or put Canada in breach of any contract with a third party or derogate from the ***Commercialization***. Notwithstanding the foregoing, Canada may still consent in exchange for payment of both [*].

18.6 No Comfort Letter

Notwithstanding anything to the contrary in the ***License Agreement***, Canada shall be under no obligation whatsoever to sign any a comfort letter or other undertaking to a third party for the benefit of the Company. If Canada so elects pursuant to its unfettered discretion, then the Company shall pay or provide security in the amount of liability so accepted or incurred by Canada.

18.7 Subcontracting

The Company has the right to subcontract any portion, but not all, of the ***License Agreement,*** subject to the following:

18.7.1 subcontracting activities (including subcontracts entered into with contract research organizations) shall be carried out by the Company in a manner that is consistent with the Company's obligations under paragraphs 2.4 to 2.7 of the ***License Agreement***;

18.7.2 the Company shall notify Canada in writing of any significant subcontracts or subcontractors of whom the Company is aware may have an interest in the technology or a collaboration with Canada;

18.7.3 the subcontract cannot be a *de facto* assignment; and

18.7.4 no rights, obligations, power or control vested in the Company shall be contingently or otherwise transferred to any third party.

18.8 No Third Party Rights

Nothing expressed or implied in the ***License Agreement*** is intended to, or shall be construed to confer on or give to, any person other than the ***Parties***, any rights or remedies under or by reason of the ***License Agreement***.

18.9 Remedies Cumulative

All rights, powers and remedies provided by the ***License Agreement*** are cumulative with, and not exclusive of, the rights, powers or remedies provided by law or equity independently of the ***License Agreement***.

18.10 Mutual Assistance

The ***Parties*** will at all times hereafter, upon every reasonable request of the other, make, do, and execute or cause to be procured, made, done, and executed, all such further acts, deeds and assurances for the carrying out of the terms, covenants and agreements of the ***License Agreement***, according to the true intent and meaning of the ***License Agreement***. These obligations shall continue post termination or expiry until all pre and post termination obligations are satisfied.

18.11 Counterpart

The ***License Agreement*** may be executed simultaneously in counterpart, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

19.0 CROWN GENERAL

19.1 No Bribes

The Company warrants that no bribe, gift, or other inducement has been paid, given, promised or offered to any Government official or employee for the obtaining of this ***License Agreement***.

19.2 No Share to Members of Parliament

Pursuant to the Parliament of Canada Act, R.S.C. 1985, c.P-1, no member of the House of Commons or Senate will be admitted to any share or part of the ***License Agreement*** or to any benefit arises from the ***License Agreement***.

19.3 Public Office Holders

It is a term of this ***License Agreement*** that no former public Office holder, who is not in compliance with the post employment provisions of the Conflict of Interest and Post Employment Code for Public Office Holders, shall derive a direct benefit from this ***License Agreement***.

20.0 NOTICE

20.1 Addresses / Contacts

Wherever in this ***License Agreement*** it is required or permitted that notice or demand be given, or served by either ***Party*** to or on the other ***Party***, such notice or demand will be in writing and will be validly given or sufficiently communicated if hand delivered or forwarded by certified mail, priority post mail, telegram, or facsimile or sent by overnight delivery by a nationally recognized courier as follows:

The addresses for delivery are:

To the Company:

Nicholas Vahanian
Chief Medical Officer
BioProtection Systems Corporation
2901 S. Loop Dr., Suite 3360
Ames, IA, USA
50010
Telephone: (515) 598-2922
Facsimile: (515) 296-3820
Email: nvahanian@linkp.com

To Canada:

Dorothea Blandford, PhD
Director, Intellectual Property Management & Business Development Operations
Public Health Agency of Canada
1015 Arlington Street, Suite 2420
Winnipeg, Manitoba
Canada R3E 3R2
Telephone: (204) 789-2096

Facsimile: (204) 789-2097
Email: dorothea_blanciford@hc-sc.dc.ca

The Parties shall send an e-mail version of the notice or demand at least 24 hours prior to the hard or facsimile copy, but failure to send the email version does not invalidate or otherwise make subsequent service of the notice defective,

20.2 Deemed Delivery

Notice will be deemed to have been delivered:

20.2.1 if delivered by hand, upon receipt;

20.2.2 if sent by electronic transmission, forty-eight (48) hours after the time of confirmed transmission, excluding from the calculation weekends and public holidays;

20.2.3 if sent by certified mail, four (4) days after the mailing thereof, provided that if there is a postal strike or other disruption, such notice will be delivered by hand or electronic transmission.

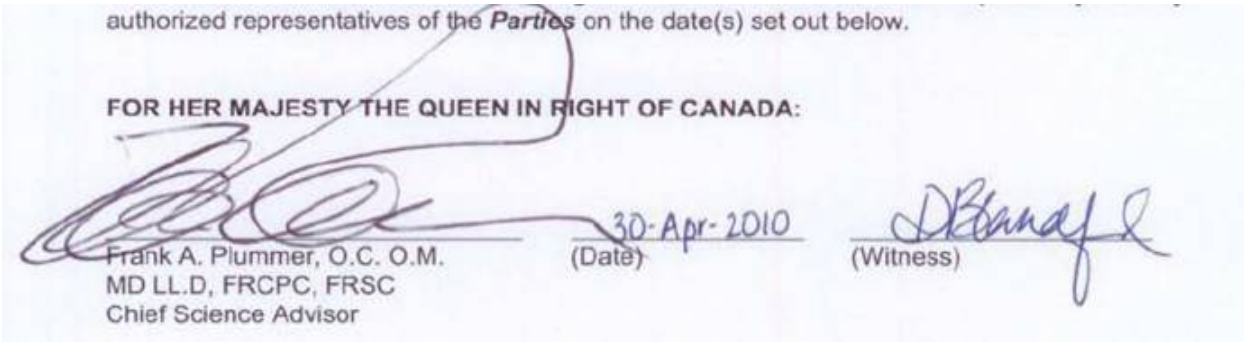
20.3 Change of Address

The ***Parties*** may change their respective addresses for delivery by delivering notice of change as provided in this paragraph.

21.0 EXECUTION

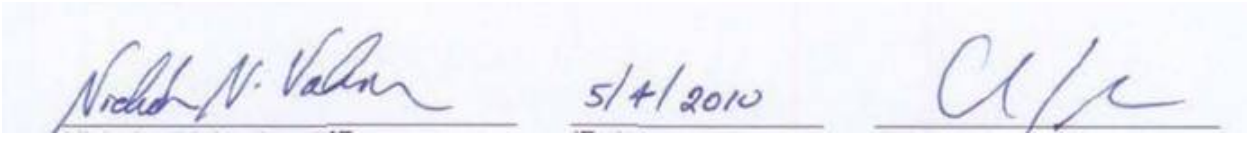
IN WITNESS WHEREOF this ***License Agreement*** has been executed in duplicate by the duly authorized representatives of the ***Parties***, on the date(s) set out below.

FOR HER MAJESTY THE QUEEN IN RIGHT OF CANADA:



Frank A. Plummer, O.C. O.M. MD LL.D, FRCPC, FRSC Chief Science Advisor	(Date)	(Witness)

FOR THE COMPANY:



Nicholas Vahanian, MD Chief Medical Officer	(Date)	(Witness)

I have authority to bind the corporation

APPENDIX "A" DESCRIPTION OF THE *LICENSED RIGHTS*

[*]Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers **[*]**.

[*]Recombinant Vesicular Stomatitis Virus Vaccines for Viral Hemorrhagic Fevers **[*]**.

APPENDIX "B" CONFIDENTIALITY AGREEMENTS

(APPENDED OVER THE NEXT 8 PAGES)

Public Health Agency of Canada | Agence de la santé publique du Canada

Office of Director
Business Development and Operations
National Microbiology Laboratory
1015 Arlington Street
Winnipeg, Manitoba R3E 3R2

April 14, 2010

Nicholas Vahanian
BioProtection Systems Corporation
Iowa Stale University Research Park,
2901 South Loop Drive, Suite 3360,
Ames, Iowa 50010

RE: Non Disclosure Agreement dated, November 18, 2008 between the Public Health Agency of Canada (referred to as "PHAC"), and BioProtection Systems Corporation (referred to as "BPS").

Dear Dr Vahanian,

PHAC and BPS have executed a Non Disclosure Agreement dated November 18, 2008. The parties hereby agree to amend the Agreement as follows:

i) Section 9C, "The term of this Agreement shall commence on its effective date and remain in force for **eighteen (18)** months thereafter, except that the Agreement shall remain effective with respect to the confidential information disclosed under this Agreement for the remainder of any period of confidentiality pursuant to subparagraph 9b above."

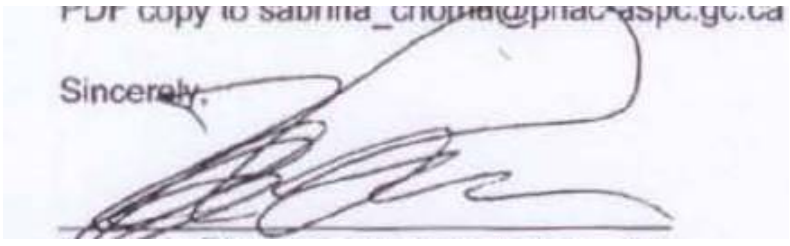
Shall be replaced by

Section 9C "The term of this Agreement shall commence on its effective date and remain in force for **sixty (60)** months thereafter, except that the Agreement shall remain effective with respect to the confidential information disclosed under this Agreement for the remainder of any period of confidentiality pursuant to subparagraph 9b above."

All other terms and conditions of the Agreement will remain in full force and effect and shall continue the duration of the Agreement. This letter, upon execution by both parties, shall form part of the Agreement and the two documents shall be read together.

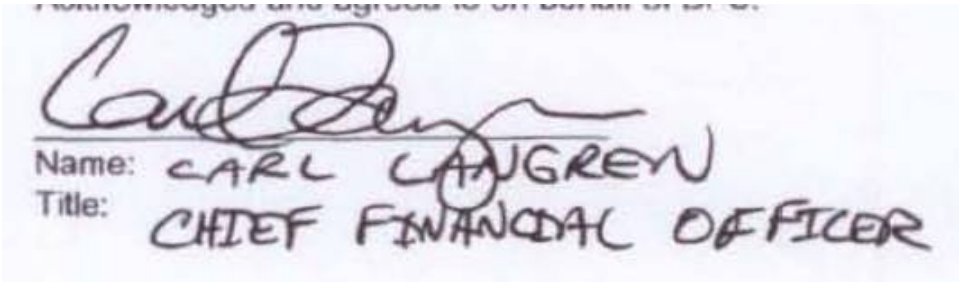
If the foregoing amendment is satisfactory, please counter sign this letter on behalf of the Participants in the spaces provided, and return the signed letter to our office via electronic PDF copy to sabrina_choma@phac-aspc.gc.ca

Sincerely,



Frank A. Plummer OC, MD, LL.D, FRCP(C), FRSC
Scientific Director General
National Microbiology Laboratory

Acknowledged and agreed to on behalf of BPS:



Name: Carl Langren
Title: Chief Financial Officer

Public Health Agency of Canada / Agence de santé publique du Canada

CONFIDENTIAL DISCLOSURE AGREEMENT

THE PARTIES ARE: Her Majesty the Queen in Right of Canada as represented by the Minister of Health ("Public Health Agency of Canada")

Whose address is:
National Microbiology Laboratory
Canadian Science Centre for Human and Animal Health Canada
1015 Arlington Street, Winnipeg, MB R3E 3R2, CANADA
(called "**PHAC**") OF THE FIRST PART

AND: BioProtection Systems Corporation

Whose address is
Iowa State University Research Park, 2901 South Loop Drive,
Suite 3360, Ames Iowa 50010
(called the "**Participant**") OF THE SECOND PART

Effective Date: November 1, 2008

In order to protect certain confidential information the Parties identified above, agree on terms about confidentiality which fairly protects both parties.

1. Disclosing Party: The party(ies) disclosing confidential information ("Disclosing Party") is/are: Public Health Agency at Canada, National Microbiology Laboratory, 1015 Arlington Street, Winnipeg. MB 133E 3R2, and BioProtection Systems Corporation, 2901 South Loop Drive, Suite 3360, Ames, Iowa 50010.

2. Primary Representative: The representative(s) of each party for coordinating the disclosure and/or receipt of confidential information are: Dr. Steven Jones and Dr. Dorothea Blandford and Dr. Nicholas Vahanian.

3. Description of Confidential Information: The subject matter of the confidential information disclosed under this Agreement is described as:
Public Health Agency of Canada: [*].
Participant: scientific and technical information relating to the pipeline products; business information.

4. Use of Confidential Information: The party receiving the confidential information ("Recipient") shall keep the confidential information in strict confidence and shall make use of the confidential information only for the following purpose: to discuss scientific and business arrangements in view of negotiating a license agreement.

5a. Standard of Care: Recipient shall protect the disclosed confidential information by using the same degree of care, but no less than a reasonable degree of care, to prevent the unauthorized

use, dissemination, or publication of the confidential information, as Recipient uses to protect its own confidential information of a like nature.

5b. In particular, and without limiting the generality of the foregoing, Recipient shall not copy, reproduce, divulge, publish or circulate (or permit anyone else to do so) any of the confidential information disclosed to it by the Disclosing Party, except to such of its employees [and/or contractors and consultants] as may require access to the confidential information on a strict need-to-know basis for the uses contemplated in paragraph 4.

6. Markings: Recipient's obligations shall extend to confidential information that is described in paragraph 3, and that (a) if set out in written, graphical, photographic or other tangible form (including, without limitation thereto, machine readable object code), is marked "Confidential' or "Proprietary" by the Disclosing Party, or (b) if disclosed orally, is identified as confidential or proprietary at the time of disclosure and a written summary thereof marked 'Confidential" or 'Proprietary" is furnished by the Disclosing Party to Recipient within thirty (30) days after such oral disclosure.

7. Exclusions: This Agreement imposes no obligation upon Recipient with respect to information that: (a) was in Recipient's possession before receipt from the Disclosing Party; (b) is or becomes a matter of public knowledge through no fault of Recipient; (c) is rightfully received by Recipient from a third party without a duty of confidentiality; (d) is disclosed by the Disclosing Party to a third party without a duty of confidentiality on the third party; (e) is independently developed by Recipient; (f) is disclosed under operation of law, including the Access to Information Act of Canada; or (g) is disclosed by Recipient with the Disclosing Party's prior written approval.

8. Warranty: Each Disclosing Party warrants that it has the right to make the disclosures under this Agreement.

NO OTHER WARRANTIES ARE MADE BY EITHER PARTY UNDER THIS AGREEMENT. ANY INFORMATION EXCHANGED UNDER THIS AGREEMENT IS PROVIDED "AS IS".

NEITHER PARTY PROVIDES ANY OTHER REPRESENTATION, WARRANTY, ASSURANCE OR GUARANTEE OF ANY KIND WITH RESPECT TO THE CONFIDENTIAL INFORMATION IT DISCLOSES.

9a. Rights: Neither party acquires any intellectual property rights under this Agreement except the limited rights necessary to carry out the purposes set forth in paragraph 4. This Agreement shall not restrict reassignment of Recipient's employees.

9b. The obligations set out in paragraphs 4 and 5 above shall become effective with respect to any confidential information immediately upon its disclosure by the Disclosing Party to Recipient and shall continue for a period of three (3) years thereafter.

9c. The term of this Agreement shall commence on its effective date and remain in force for 18 months thereafter, except that the Agreement shall remain effective with respect to the

confidential information disclosed under this Agreement for the remainder of any period of confidentiality pursuant to subparagraph 9b above.

9d. Upon request made by the Disclosing Party during the term of the Agreement, Recipient shall return the confidential information and all copies thereof to the Disclosing Party or, at the option of the Disclosing Party, destroy the confidential information and all copies thereof, and Recipient shall certify in writing within five (5) days of the receipt of the request from the Disclosing Party that it has complied with that request.

Miscellaneous

10. The only terms concerning confidentiality relating to the information described in paragraph 3 are in this Agreement and in the Access to Information Act of Canada.

11. This Agreement imposes no obligation on either party to purchase, sell, licence, transfer or otherwise dispose of any technology, services or products, and neither this Agreement nor the disclosure or receipt of confidential information under this Agreement constitutes or implies any undertaking or commitment by either party to enter into any further activity, arrangement or course of action with the other party or with any third party.

12. Both parties shall adhere to all applicable laws, regulations and rules relating to the export of technical data, and shall not export or re-export any technical data, any products received from the Disclosing Party, or the direct product of such technical data to any prescribed country listed in such applicable laws, regulations and rules unless properly authorized.

13. This Agreement does not create any agency or partnership relationship.

14. This Agreement cannot be modified except by a document signed by both Parties that explicitly refers to this Agreement.

SIGNED by the Participant in duplicate at Ames, Iowa

This 18th day of November 2007 sc

BioProtection Systems Corporation

Per _____

Nicholas N. Vahanian, M.D.
Chief Medical Officer,

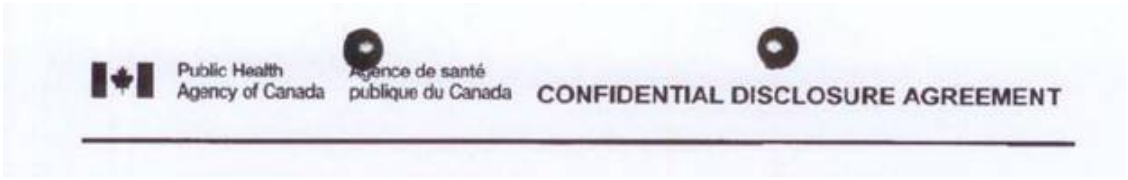
SIGNED by the Public Health Agency of Canada in duplicate at Winnipeg, Manitoba

This 1 day of November 2007

Her Majesty the Queen in Right of Canada as Represented by the Minister of Health

Per: _____

Frank A Plummer, OC, MD, LLD, FRCP (C), FRSC
Scientific Director General
National Microbiology Laboratory



THE PARTIES ARE: Her Majesty the Queen in Right of Canada as represented by the Minister of Health ("Public Health Agency of Canada")

Whose address is
National Microbiology Laboratory
Canadian Science Centre for Human and Animal Health Canada
1015 Arlington Street, Winnipeg, MB R3E 3R2, CANADA
(called "**PHAC**") OF THE FIRST PART

AND: BioProtection Systems Corporation

Whose address is
Iowa State University Research Park, 2901 South Loop Drive,
Suite 3360, Ames Iowa 50010
(called the "**Participant'**) OF THE SECOND PART

Effective Date: May 1, 2007

In order to protect certain confidential information the Parties identified above, agree on terms about confidentiality which fairly protects both parties.

1. Disclosing Party: The party(ies) disclosing confidential information ("Disclosing Party") is/are: Public Health Agency of Canada, National Microbiology Laboratory, 1015 Arlington Street, Winnipeg, MB R3E 3R2, and BioProtection Systems Corporation, 2901 South Loop Drive, Suite 3360, Ames, Iowa 50010.

2. Primary Representative. The representative(s) of each party for coordinating the disclosure and/or receipt of confidential information are: Dr. Heinz Feldmann and Dr. Dorothea Blandford and Dr. Nicholas Vahanian.

3. Description of Confidential Information: The subject matter of the confidential information disclosed under this Agreement is described as:
Public Health Agency of Canada: [*]
Participant: scientific and technical information relating to the pipeline products: business information.

4. Use of Confidential Information: The party receiving the confidential information ("Recipient") shall keep the confidential information in strict confidence and shall make use of the confidential information only for the following purpose: to discuss scientific and business arrangements in view of negotiating a license agreement.

5a. Standard of Care: Recipient shall protect the disclosed confidential information by using the same degree of care, but no less than a reasonable degree of care, to prevent the unauthorized use, dissemination, or publication of the confidential information, as Recipient uses to protect its own confidential information of a like nature.

5b. In particular, and without limiting the generality of the foregoing, Recipient shall not copy, reproduce, divulge, publish or circulate (or permit anyone else to do so) any of the confidential information disclosed to it by the Disclosing Party, except to such of its employees [and/or contractors and consultants] as may require access to the confidential information on a strict need-to-know basis for the uses contemplated in paragraph 4.

6 Markings: Recipient's obligations shall extend to confidential information that is described in paragraph 3, and that (a) if set out in written, graphical, photographic or other tangible form (including, without limitation thereto, machine readable object code), is marked "Confidential" or "Proprietary" by the Disclosing Party, or (b) if disclosed orally, is identified as confidential or proprietary at the time of disclosure and a written summary thereof marked "Confidential" or "Proprietary" is furnished by the Disclosing Party to Recipient within thirty (30) days after such oral disclosure.

7. Exclusions: This Agreement imposes no obligation upon Recipient with respect to information that: (a) was in Recipient's possession before receipt from the Disclosing Party; (b) is or becomes a matter of public knowledge through no fault of Recipient; (c) is rightfully received by Recipient from a third party without a duty of confidentiality: (d) is disclosed by the Disclosing Party to a third party without a duty of confidentiality on the third party; (e) is independently developed by Recipient; (1) is disclosed under operation of law, including the Access to information Act of Canada; or (g) is disclosed by Recipient with the Disclosing Party's prior written approval.

8. Warranty: Each Disclosing Party warrants that it has the right to make the disclosures under this Agreement.

NO OTHER WARRANTIES ARE MADE BY EITHER PARTY UNDER THIS AGREEMENT, ANY INFORMATION EXCHANGED UNDER THIS AGREEMENT IS PROVIDED "AS IS".

NEITHER PARTY PROVIDES ANY OTHER REPRESENTATION, WARRANTY, ASSURANCE OR GUARANTEE OF ANY KIND WITH RESPECT TO THE CONFIDENTIAL INFORMATION IT DISCLOSES.

9a. Rights: Neither party acquires any intellectual property rights under this Agreement except the limited rights necessary to carry out the purposes set forth in paragraph 4. This Agreement shall not restrict reassignment of Recipient's employees.

9b. The obligations set out in paragraphs 4 and 5 above shall become effective with respect to any confidential information immediately upon its disclosure by the Disclosing Party to Recipient and shall continue for a period of three (3) years thereafter.

9c. The term of this Agreement shall commence on its effective date and remain in force for 18 months thereafter, except that the Agreement shall remain effective with respect to the confidential information disclosed under this Agreement for the remainder of any period of confidentiality pursuant to subparagraph 9b above.

9d. Upon request made by the Disclosing Party during the term of the Agreement, Recipient shall return the confidential information and all copies thereof to the Disclosing Party or, at the option of the Disclosing Party, destroy the confidential information and all copies thereof, and Recipient shall certify in writing within five (5) days of the receipt of the request from the Disclosing Party that it has complied with that request.

Miscellaneous

10. The only terms concerning confidentiality relating to the information described in paragraph 3 are in this Agreement and in the Access to Information Act of Canada.

11. This Agreement imposes no obligation on either party to purchase, sell, licence, transfer or otherwise dispose of any technology, services or products, and neither this Agreement nor the disclosure or receipt of confidential information under this Agreement constitutes or implies any undertaking or commitment by either party to enter into any further activity, arrangement or course of action with the other party or with any third party.

12. Both parties shall adhere to all applicable laws, regulations and rules relating to the export of technical data, and shall not export or re-export any technical data, any products received from the Disclosing Party, or the direct product of such technical data to any prescribed country listed in such applicable laws, regulations and rules unless properly authorized.

13. This Agreement does not create any agency or partnership relationship

14. This Agreement cannot be modified except by a document signed by both Parties that explicitly refers to this Agreement.

SIGNED by the Participant in duplicate at Ames, Iowa

This 30th day of April 2007

BioProtection Systems Corporation

Per Nicholas N. Vahanian

Nicholas N. Vahanian, M.D.
Chief Medical Officer,

SIGNED by the Public Health Agency of Canada in duplicate at Winnipeg, Manitoba

This 27 day of April 2007

Her Majesty the Queen in Right of Canada as Represented by the Minister of Health

Per:

Frank A Plummer, OC, MD, LLD, FRCP (C), FRSC
Scientific Director General
National Microbiology Laboratory

APPENDIX "C" BUSINESS PLAN

(TO FOLLOW WITHIN 30 DAYS OF EXECUTION)

APPENDIX "D" AFFILIATES

NewLink Genetics Corporation, 2901 South Loop Drive, Suite 3900, Ames, Iowa, USA 50010

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES 1 33
2. CONTRACT (Proc. Inst. Ident) NO. HDTRA1-09-C-0014	3. EFFECTIVE DATE 25 Sep 2009	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE	

5. ISSUED BY CODE HDTRA1	6. ADMINISTERED BY (If other than Item 5) CODE S2401A
DEFENSE THREAT REDUCTION AGENCY/BE-BC 8725 JOHN J. KINGMAN ROAD, MSC 6201 FORT BELVOIR VA 22060-6201	DCMA TWIN CITIES B.H. WHIPPLE FEDERAL BLDG., RM 1150 FT. SNELLING MN 55111

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY [ ] FOB ORIGIN [X] OTHER (see below)
BIOPROTECTION SYSTEMS CORPORATION DR. CHARLES LINK 2901 S LOOP DR STE 3360 AMES IA 50010-8646	9. DISCOUNT FOR PROMPT PAYMENT
	10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ITEM
CODE 47EJ3 FACILITY CODE	

11. SHIP TO/MARK FOR CODE HDTRA1	12. PAYMENT WILL BE MADE BY CODE HQ0339
DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MSC 6201 FORT BELVOIR VA 22060-6201	DFAS COLUMBUS CENTER DFAS-CO/WEST ENTITLEMENT OPERATIONS P.O. BOX 182381 COLUMBUS OH 43218-2381

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
[ ] 10 U.S.C. 2304(c) ( ) [ ] 41 U.S.C. 253(c) ( )	See Schedule

15A. ITEM NO.	15B. SUPPLIES / SERVICES	15C. QUANTITY	15D. UNIT.	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				
			15G. TOTAL AMOUNT OF CONTRACT		$3,707,837.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC	DESCRIPTION	PAGE(S)
		PART I – THE SCHEDULE				**PART II – CONTRACT CLAUSES**	
X	A	SOLICITATION/CONTRACT FORM	1	X	I	CONTRACT CLAUSES	15 -32
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2 - 4			**PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	5	X	J	LIST OF ATTACHMENTS	33
X	D	PACKAGING AND MARKING	6			**PART IV – REPRESENTATIONS AND INSTRUCTIONS**	
X	E	INSPECTION AND ACCEPTANCE	7		K	REPRESENTATIONS CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	8				
X	G	CONTRACT ADMINISTRATION DATA	9 - 13		L	INSTRS. CONDS. AND NOTICES TO OFFERORS	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign (this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)	18. [ ] AWARD (Contractor is not required to sign this document.). Your offer on Solicitation Number _____ Including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract,. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME AND TITLE OF CONTRACTING OFFICER
Carl Langren, Chief Financial Officer	ALYNNE FAUGHNAN / CONTRACT SPECIALIST TEL EMAIL: alynne.Faughnan@dtra.mil

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
By: /s/ Carl Langren (Signature of person authorized to sign)	9/21/09	By: /s/Alynne Faughnan (Signature of Contracting Officer)	9-21-09

NSN 7540-01-152-8069 26-107 STANDARD FORM 26 (REV. 12/2002)

Previous edition is usable GPO 1985 O – 469-794 Prescribed by GSA PAR (48 CFR) 53.214(a)

Section B - Supplies or Services and Prices

BAA REFERENCE

This contract is awarded as a result of Solicitation HDTRA1-07-RDINO-BAA, Broad Agency Announcement.

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Lot		$ 3,707,837.00
	Base Period				
	CPFF				
	In accordance with Statement of Work entitled “aGal Adjuvant Technology for Biodefense Agents,” dated March 15, 2009 as attachment number one.				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				

				ESTIMATED COST	$ 3,408,767.00
				FIXED FEE	$ 299,070.00
				TOTAL EST COST + FEE	$ 3,707,837.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$ 0.00
	Base Period Funding				
	CPFF				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				
				ESTIMATED COST	$ 0.00
				FIXED FEE	$ 0.00
				TOTAL EST COST + FEE	$ 0.00
	ACRN AA				$ 1,429,820.00
	CIN: CBS080011915000101				

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$ 0.00
	Base Period Funding				
	CPFF				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBM09001379				
				ESTIMATED COST	$ 0.00
				FIXED FEE	$ 0.00
				TOTAL EST COST + FEE	$ 0.00
	ACRN AB				$ 2,278,017.00
	CIN: CBM090013719000102				

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002					NSP
	Contract Data Requirements List				
	CPFF				
	CDRLS IAW attachment 1				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: CBS080011915				
				ESTIMATED COST	$ 0.00
				FIXED FEE	$ 0.00
				TOTAL EST COST + FEE	$ 0.00

See Exhibit A

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003			Lot		$ 6,891,784.00
OPTION	Option Year One				
	CPFF				
	FOB: Destination				
				ESTIMATED COST	$ 6,705,742.00
				FIXED FEE	$ 186,042.00
				TOTAL EST COST + FEE	$ 6,891,784.00

Section C - Descriptions and Specifications

CLAUSES INCORPORATED BY FULL TEXT

252.211-9000 Description/Specifications/Work Statement

The Contractor shall provide the supplies and/or services set forth in Section B, in accordance with the following:

a. Statement of Work entitled "*a*Gal adjuvant Technology for Biodefense Agents", Dated March 15, 2009, Attachment 1 to the Contract.

b. Contract Data Requirements List (DD Form 1423), Exhibit A to the Contract.

Section D - Packaging and Marking

CLAUSES INCORPORATED BY FULL TEXT

252.247-9001 PACKAGING AND MARKING

(a) All data contained in Exhibit A, Contract Data Requirements List (CDRL), DD Form 1423 delivered under this contract shall be delivered using best commercial practices to meet the packaging requirements of the carrier and to insure delivery, to the addressees specified on the Data Item Cover Sheet, at destination and in accordance with applicable security requirements.

(b) All data and correspondence submitted to the Contracting Officer shall reference the Contract Number, the CDRL number, and the date submitted. A copy of all correspondence sent to the Contracting Officer's Representative (COR) or Project Manager shall be simultaneously provided to the Contracting Officer.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	Destination	Government	Destination	Government
000102	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY FULL TEXT

252.246-9000 INSPECTION AND ACCEPTANCE (JUL 2007)

Government inspection and acceptance of data is specified on the Contract Data Requirements List, DD Form 1423. In accordance with FAR 52.246-9, inspection and acceptance for all work performed at any and all times under this contract shall be the responsibility of the:

x Contracting Officer's Representative (COR) or Project Manager (PM). The Wide Area Work Flow (WAWF) Acceptor DoDDAC is located in DTRA 252.201-9000 *Project Manager* or DTRA 252.201-9002 *Contracting Officer's Representative*.

o Administrative Contracting Officer (ACO). The WAWF Acceptor DoDAAC can be found in the "Administered By" block on page 1 of the contract.

(End of Clause)

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	POP 25-SEP-2009 TO 24-SEP-2011	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
0002	POP 25-SEP-2009 TO 24-SEP-2012	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1
0003	POP 25-SEP-2011 TO 24-SEP-2012	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	HDTRA1

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.247-34	F.O.B. Destination	NOV 1991

Section G - Contract Administration Data

ADMINISTRATION

ASSIGNMENT OF CONTRACT ADMINISTRATION SERVICES (CAS) FUNCTIONS (AUG 2007)

a. The contract administration functions stated in FAR 42.302(a) are assigned to:
See Section A, Block 6.

b. Notwithstanding that assignment, in accordance with FAR 42.202(b)(2), the following functions are determined to be best performed by the PCO and are retained by the DTRA Contracting Office:

(1) FAR 42.302(a)(3) Conduct postaward orientation conferences.

(2) FAR 42.302(a)(20) Perform Postaward Security Administration.

(3) FAR 42.302(a)(40) Perform engineering surveillance to assess compliance with contractual terms for schedule, cost, and technical performance in the areas of design, development, and production.

(4) FAR 42.302(a)(51) In accordance with FAR 52.244-2, consent to the placement of subcontracts which have experimental, developmental, or research work as one of its purposes.

(5) Approval or disapproval of the data items listed on Exhibit A, DD Form 1423, Contract Data Requirements List.

(END OF CLAUSE)

ACCOUNTING AND APPROPRIATION DATA

AA: 9780400.2620 1000 B62D 255999 BD27846000 S49012
AMOUNT: $1,429,820.00
CIN CBS080011915000101: $1,429,820.00

AB: 9790400.2620 1000 B62D 255999 BD29356000 S49012
AMOUNT: $2,278,017.00
CIN CBM090013719000102: $2,278,017.00

CLAUSES INCORPORATED BY FULL TEXT

252.201-9002 CONTRACTING OFFICER'S REPRESENTATIVE (MAY 2007)

a. The Contracting Officer's Representative (COR) for this contract is:

x **SEE SEPARATE LETTER**
Defense Threat Reduction Agency/
8725 John J. Kingman Rd, MS 6201
Fort Belvoir VA 22060-6201
Telephone number (703)
e-mail address @dtra.mil.
WAWF Acceptor DoDAAC: HDTRA1

Defense Threat Reduction Agency/
1680 Texas St SE
Kirtland AFB NM 87117-5669
Telephone number (505) -
e-mail address @abq.dtra.mil.
WAWF Acceptor DoDAAC: HDTRA2

b. The COR will act as the Contracting Officer's Representative for technical matters providing technical direction and discussion as necessary with respect to the specification/statement of work and monitoring the progress and quality of the Contractor's performance. The COR is NOT an Administrative Contracting Officer (ACO) and does not have the authority to take any action, either directly or indirectly that would change the pricing, quality, quantity, place of performance, delivery schedule, or any other terms and conditions of the contract, or to direct the accomplishment of effort, which goes beyond the scope of the specifications/statement of work in the contract.

c. When, in the opinion of the contractor, the COR requests effort outside the existing scope of the contract, the contractor shall promptly notify the Contracting Officer in writing. No action shall be taken by the contractor under such direction until the Contracting Officer has issued a modification to the contract or has otherwise resolved the issue.

CLAUSES INCORPORATED BY FULL TEXT

252.204-9002 PAYMENT INSTRUCTIONS FOR MULTIPLE ACCOUNTING CLASSIFICATION CITATIONS (AUG 2007)

In accordance with DFARS 204.7108 *Payment Instructions*, payment shall be made by the numbered payment instruction identified below:

o (1) *Line item specific: single funding.* If there is only one source of funding for the contract line item (i.e., one ACRN), the payment office will make payment using the ACRN funding of the line item being billed.

o (2) *Line item specific: sequential ACRN order*. If there is more than one ACRN within a contract line item, the payment office will make payment in sequential ACRN order within the line item, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: Alpha/Alpha; Alpha/Numeric; Numeric/Alpha; and Numeric/Numeric.

o (3) *Line item specific: contracting officer specified ACRN order*. If there is more than one ACRN within a contract line item, the payment office will make payment within the line item in the sequence

ACRN order specified by the contracting officer, exhausting all funds in the previous ACRN before paying from the next ACRN.

x (4) *Line item specific: by fiscal year*. If there is more than one ACRN within a contract line item, the payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year.

o (5) *Line item specific: by cancellation date*. If there is more than one ACRN within a contract line item, the payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date.

o (6) *Line item specific: proration*. If there is more than one ACRN within a contract line item, the payment office will make payment from each ACRN in the same proportion as the amount of funding currently unliquidated for each ACRN.

o (7) *Contract-wide: sequential ACRN order.* The payment office will make payment in sequential ACRN order within the contract or order, exhausting all funds in the previous ACRN before paying from the next ACRN using the following sequential order: alpha/alpha; alpha/numeric; numeric/alpha; and numeric/numeric.

o (8) *Contract-wide: contracting officer specified ACRN order*. The payment office will make payment in sequential ACRN order within the contract or order, exhausting all funds in the previous ACRN before paying from the next ACRN in the sequence order specified by the contracting officer.

o (9) *Contract-wide: by fiscal year*. The payment office will make payment using the oldest fiscal year appropriations first, exhausting all funds in the previous fiscal year before disbursing from the next fiscal year. In the event there is more than one ACRN associated with the same fiscal year, the payment amount shall be disbursed from each ACRN within a fiscal year in the same proportion as the amount of funding obligated for each ACRN within the fiscal year.

o (10) *Contract-wide: by cancellation date*. The payment office will make payment using the ACRN with the earliest cancellation date first, exhausting all funds in that ACRN before disbursing funds from the next. In the event there is more than one ACRN associated with the same cancellation date, the payment amount shall be disbursed from each ACRN with the same cancellation date in the same proportion as the amount of funding obligated for each ACRN with the same cancellation date.

o (11) *Contract-wide: proration*. The payment office will make payment from each ACRN within the contract or order in the same proportion as the amount of funding currently unliquidated for each ACRN.

o (12) *Other*. If none of the standard payment instructions identified in paragraphs (d)(1) through (11) of this section are appropriate, the contracting officer may insert other payment instructions, provided the other payment instructions—

(i) Provide a significantly better reflection of how funds will be expended in support of contract performance; and
(ii) Are agreed to by the payment office and the contract administration office.

CLAUSES INCORPORATED BY FULL TEXT

252.232-9007 PAYMENT INFORMATION IN CENTRAL CONTRACTOR REGISTRATION (CCR) DATABASE

This contract contains FAR clause 52.204-7, Central Contractor Registration. All contractors must be registered in the CCR database prior to award, during performance, and through final payment of any contract, except for awards to foreign vendors for work to be performed outside the United States.

The Contractor is responsible for the accuracy and completeness of the data within the CCR, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. In addition to the contractor's requirement to confirm on an annual basis that its information in the CCR database is accurate and complete, the contractor's information in the CCR database must be updated whenever changes occur to the contractor's remit-to data (e.g., account number, vendor name and address, etc.) and the paying office notified of any changes. The contractor's failure to maintain accurate information in the CCR database could result in payment delays for which the Government shall not be liable.

CLAUSES INCORPORATED BY FULL TEXT

252.232-9012 WIDE AREA WORK FLOW (WAWF) — RECEIPT AND ACCEPTANCE (RA) INSTRUCTIONS (December 2007)

(a) As prescribed in DFARS clause 252.232-7003 Electronic. Submission of Payment Requests (Jan 2004), Contractors must submit payment requests in electronic form. Paper copies will no longer be accepted or processed for payment unless the conditions of DFARS clause 252.232-7003(c) apply. To facilitate this electronic submission, the Defense Threat Reduction Agency (DTRA) has implemented the DoD sanctioned Wide Area Workflow-Receipt and Acceptance (WAWF-RA) for contractors to submit electronic payment requests and receiving reports. The contractor shall submit electronic payment requests and receiving reports via WAWF-RA. **Vendors shall send an email notification to the Contracting Officer Representative (COR), Program/Project Manager or other government acceptance official identified in the contract by clicking on the Send More Email Notification link upon submission of an invoice/cost voucher in WAWF-RA. To access WAWF, go to https://wawf.eb.mil//.**

**** For questions, contact the DTRA WAWF Team at 703-767-6840 or wawfhelp@dtra.mil ****

(b) Definitions:

Acceptor: Contracting Officer's Representative, Program/Project Manager, or other government acceptance official as identified in the contract/order.

Pay Official: Defense Finance and Accounting Service (DFAS) payment office identified in the contract/order.

SHIP To/Service Acceptor DoDAAC: Acceptor DoDAAC or DCMA DoDAAC (as specified in the contract/order).

DCAA Auditor DoDAAC: Needed when invoicing on cost-reimbursable contracts. (Go to www.dcaa.mil and click on the appropriate link under the Audit Office Locator to search for your DCAA DoDAAC.)

>>> For contracts that are administered by the **Office of Naval Research (ONR):** <<<
Enter the ONR DoDAAC in the DCAA Auditor DoDAAC field in WAWF.

(c) WAWF Contractor Input Information:

The contractor shall use the following information in creating electronic payment requests in WAWF:

Invoice Type in WAWF:

If billing for Cost Type/Reimbursable contracts (including T&M and LH), select "Cost Voucher"
If billing for Firm-Fixed Price Materials Only, select "Combo"
If billing for Firm-Fixed Price Materials and Service, select "Combo"
If billing for Firm-Fixed Price Services Only, select "2-n-1 (Services Only)"

For WAWF Routing Information, See Table Below:

Description	SF 26	SF 33	SF 1449	DD 1155
	Located in Block/Section			
Contract Number	2	2	2	1
Delivery Order	See Individual Order		4	2
CAGE Code	7	15a	17a	9
Pay DoDAAC	12	25	18a	15
Inspection	Section E (except SF 1449, See Entitled): INSPECTION AND ACCEPTANCE			
Acceptance	Section E (except SF 1449, See Entitled): INSPECTION AND ACCEPTANCE			
Issue Date	3	5	3	3
Issue by DoDAAC	5	7	9	6
Admin DoDAAC	6	24	16	7
Ship To / Service Acceptor DoDAAC	6	24	16	7
Ship to Extension	Do Not Fill In			
Services or Supplies	Based on majority of requirement as determined by monetary value			
Final Invoice?	Do not change "N" (no) to "Y" (yes) unless this is the last invoice and the contract is ready for closeout.			

(d) Final Invoices/Vouchers -Final Payment shall be made in accordance with the Federal Acquisition Regulation (FAR) 52.216-7, entitled "Allowable Cost and Payment."

Invoices - Invoice 2-n-1 (Services Only) and Invoice and Receiving Report (Combo)
Select the ***"Y"*** selection from the ***"Final Invoice?"*** drop-down box when submitting the final invoice for payment for a contract. Upon successful submission of the final invoice, click on the ***Send More Email Notifications*** link to send an additional email notification to the Contracting Officer Representative

(COR), Program/Project Manager or other government acceptance official identified in the contract.

Cost Vouchers - Once the final DCAA audit is complete for cost reimbursable contracts and authorization is received to submit the final cost voucher, select the ***"Y"*** selection from the ***"Final Voucher"*** drop-down box when submitting the final cost voucher. Upon successful submission of the final cost voucher, click on the ***Send More Email Notifications*** link to send an additional email notification to the following email address: finalcostvouchers@dtra.mil

(e) WAWF Training may be accessed online at http://www.wawftraining.com//. To practice creating documents in WAWF, visit practice site at https://wawftraining.eb.mil//. General DFAS information may be accessed using the DFAS website at http://www.dod.mil/dfas//. Payment status information may be accessed using the myInvoice system at https://myinvoice.csd.disa.mil// or by calling the DFAS Columbus

helpdesk at 800-756-4571. (Select Option 1) Your contract number and shipment/invoice number will be required to check status of your payment. **Note: For specific invoice related inquiries email: wawfvendorpay@dtra.mil. Vendors shall forward any additional DTRA related WAWF questions to wawfhelp@dtra.mil.**

Section H - Special Contract Requirements

H.1 PATENT RIGHTS
RETENTION BY THE CONTRACTOR

In accordance with FAR 52.227-11 (f), reporting on utilization of subject inventions:

The Contractor agrees to submit, periodic reports annually on the utilization of a subject invention or efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	JUL 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	SEP 2007
52.203-13	Contractor Code of Business Ethics and Conduct	DEC 2007
52.203-14	Display of Hotline Poster(s)	DEC 2007
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-7	Central Contractor Registration	APR 2008
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	SEP 2006
52.215-2	Audit and Records—Negotiation	JUN 1999
52.215-8	Order of Precedence—Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-12	Subcontractor Cost or Pricing Data	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.216-7	Allowable Cost And Payment	DEC 2002
52.216-8	Fixed Fee	MAR 1997
52.217-9	Option To Extend The Term Of The Contract	MAR 2000
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-28	Post-Award Small Business Program Rerepresentation	JUN 2007
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEPT 2006
52.222-36	Affirmative Action For Workers With Disabilities	JUN 1998
52.222-37	Employment Reports On Special Disabled Veterans, Veterans Of The Vietnam Era, and Other Eligible Veterans	SEPT 2006
52.222-39	Notification of Employee Rights Concerning Payment of Union Dues or Fees	DEC 2004
52.222-50	Combating Trafficking in Persons	AUG 2007

52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1 Alt I	Authorization And Consent (Dec 2007) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-11 Alt II	Patent Rights—Ownership by the Contractor (Dec 2007) — Alternate II	DEC 2007
52.228-7	Insurance—Liability To Third Persons	MAR 1996
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	JUN 1996

52.232-20	Limitation Of Cost	APR 1984
52.232-23 Alt I	Assignment of Claims (Jan 1986) - Alternate I	APR 1984
52.232-25 Alt I	Prompt Payment (Oct 2003) Alternate I	FEB 2002
52.232-33	Payment by Electronic Funds Transfer—Central Contractor Registration	OCT 2003
52.233-1 Alt I	Disputes (Jul 2002) - Alternate I	DEC 1991
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.243-2 Alt V	Changes—Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.244-2	Subcontracts	JUN 2007
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	MAR 2007
52.245-1	Government Property	JUN 2007
52.245-9	Use And Charges	JUN 2007
52.246-9	Inspection Of Research And Development (Short Form)	APR 1984
52.246-25	Limitation Of Liability—Services	FEB 1997
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.251-1	Government Supply Sources	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2004
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	JAN 2009
252.204-7000	Disclosure Of Information	DEC 1991
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	SEP 2007
252.204-7009	Requirements Regarding Potential Access to Export-Controlled Items	JUL 2008
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7007	Reporting of Government-Furnished Equipment in the DoD Item Unique Identification (IUID) Registry	NOV 2008
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7002	Cost Estimating System Requirements	DEC 2006
252.215-7004	Excessive Pass-Through Charges	MAY 2008
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	MAY 2007
252.225-7012	Preference For Certain Domestic Commodities	MAR 2008
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	SEP 2004
252.227-7013	Rights in Technical Data—Noncommercial Items	NOV 1995
252.227-7016	Rights in Bid or Proposal Information	JUN 1995
252.227-7025	Limitations on the Use or Disclosure of Government- Furnished Information Marked with Restrictive Legends	JUN 1995
252.227-7027	Deferred Ordering Of Technical Data Or Computer Software	APR 1988
252.227-7030	Technical Data—Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 1999
252.227-7039	Patents—Reporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008

252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7002	Animal Welfare	DEC 1991
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	NOV 2004
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	JAN 2007
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor on or before the expiration of the contract basic period. The Government will give the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36-Months.

(End of clause)

52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed $0.00 or the overtime premium is paid for work —

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall—

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

* Insert either “zero” or the dollar amount agreed to during negotiations. The inserted figure does not apply to the exceptions in paragraph (a)(1) through (a)(4) of the clause.

(End of clause)

52.249-14 EXCUSABLE DELAYS (APR 1984)

(a) Except for defaults of subcontractors at any tier, the Contractor shall not be in default because of any failure to perform this contract under its terms if the failure arises from causes beyond the control and without the fault or negligence of the Contractor. Examples of these causes are (1) acts of God or of the public enemy, (2) acts of the Government in either its sovereign or contractual capacity, (3) fires, (4) floods, (5) epidemics, (6) quarantine restrictions, (7) strikes, (8) freight embargoes, and (9) unusually severe weather. In each instance, the failure to perform must be beyond the control and without the fault or negligence of the Contractor. “Default” includes failure to make progress in the work so as to endanger performance.

(b) If the failure to perform is caused by the failure of a subcontractor at any tier to perform or make progress, and if the cause of the failure was beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either, the Contractor shall not be deemed to be in default, unless—

(1) The subcontracted supplies or services were obtainable from other sources;

(2) The Contracting Officer ordered the Contractor in writing to purchase these supplies or services from the other source; and

(3) The Contractor failed to comply reasonably with this order.

(c) Upon request of the Contractor, the Contracting Officer shall ascertain the facts and extent of the failure. If the Contracting Officer determines that any failure to perform results from one or more of the causes above, the delivery schedule shall be revised, subject to the rights of the Government under the termination clause of this contract.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://farsite.hill.af.mil/

(End of clause)

252.201-9003 LIMITATION OF AUTHORITY

No person in the Government, other than a Contracting Officer, has the authority to provide direction to the Contractor, which alters the Contractor's obligations or changes this contract in any way. If any person representing the Government, other than a Contracting Officer, attempts to alter contract obligations, change the contract specifications/statement of work or tells the contractor to perform some effort which the Contractor believes to be outside the scope of this contract, the Contractor shall immediately notify the Procuring Contracting Officer (PCO). Contractor personnel shall not comply with any order or direction which they believe to be outside the scope of this contract unless the order or direction is issued by a Contracting Officer.

252.203-9004 ETIOLOGIC AGENTS — BIOLOGICAL DEFENSE RESEARCH PROGRAM (FEB 2008)

a. For purpose of this contract etiologic agent—biological defense program is defined as: any viable microorganism, or its toxin which causes or may cause human disease, including those agents listed in 42 CFR 73, 9 CFR 121, and 7 CFR 331, of the Department of Health and Human Services and Department of Agriculture regulations, respectively, and any agent of biological origin that poses a degree of hazard to those agents and is further identified by the US Army. The contractor shall comply with the following when working with etiologic agents:

   (1) 29 Code of Federal Regulations 1910, Occupational Health and Safety;
   (2) US Department of Health and Human Services (DHHS) and US Department of Agriculture, Select Agent Program(s), 42 CFR 73, 9 CFR 121, and 7 CFR 331; and
   (3) DHHS Publication No. 93-8395, Biosafety in Microbiological and Biomedical Laboratories, latest edition.

b. Etiologic agents shall be packaged, labeled, shipped, and transported in accordance with applicable Federal, State, and local laws and regulations, to include:

   (1) 42 CFR 72 (Interstate Shipment of Etiologic Agents);
   (2) 49 CFR 172 and 173 (Department of Transportation);
   (3) 9 CFR 122 (USDA Restricted Animal Pathogens);
   (4) International Air Transport Association Dangerous Goods Regulations;
   (5) The United States Postal Service shall not be used for transportation of BDRP related etiologic agents; and
   (6) If performance is outside of the United States, any additional procedures required by the nation where the work is to be performed.

252.204-9004 IMPLEMENTATION OF DISCLOSURE OF INFORMATION (JUN 2007)

In accordance with DFARS 252.204-7000 Disclosure of Information, any information to be released shall be submitted at least 45 days before the proposed release date, for security and policy review. Submit one copy to each below:

(a) Office of Public Affairs, DTRA/DIR/COS/PA, 8725 John J. Kingman Dr, MS 6201, Ft Belvoir VA 22060-6201.
(b) Contracting Officer
(c) Program Manager
(d) Task Order Manager

(End of Clause)

252.209-9002 NON-GOVERNMENT SUPPORT PERSONNEL (JAN 2008)

The following companies may have access to contractor information, technical data or computer software that may be marked as proprietary or otherwise marked with restrictive legends: Suntiva LLC (Formerly C-Systems International Corporation)(contract specialist support); Systems Research and Analysis (SRA, managing JPRAS)and The Tauri Group (Advisory and Assistance Services). Each contract contains organizational conflict of interest provisions and/or includes contractual requirements for non-disclosure of proprietary contractor information or data/software marked with restrictive legends. The contractor, by submitting a proposal or entering into this contract, is deemed to have consented to the disclosure of its information to Suntiva LLC, SRA, and The Tauri Group under the conditions and limitations described herein.

252.215-9004 KEY PERSONNEL (FEB 2000)

The personnel listed below are considered essential to the work being performed hereunder. Prior to removing, replacing, or diverting any of the specified individuals, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on this Contract. No deviation shall be made by the Contractor without the prior written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing the change, such ratification shall constitute the consent of the Contracting Officer required by this paragraph. The personnel listed below may, with the consent of the contracting parties, be amended from time to time during the course of the Contract to either add or delete personnel as appropriate.

Principal Investigator

252.216-9003 CONSULTANTS (OCT 1998)

Services of consultants shall be at rates and for periods approved in advance by the Contracting Officer. Requests for approval shall be submitted to the Contracting Officer sufficiently in advance of the need to use a consultant under this Contract. The request shall include (a) a copy of the proposed consultant agreement, (b) a brief biography of the consultant, and (c) an indication of the area(s) in which consultant's expertise will be utilized and why it is essential for contract performance. In addition, significant deviations from the dollar amount approved for consultant services, or changes in the

consultants to be utilized, must likewise be approved in advance upon submission of adequate justification.

252.227-7013 RIGHTS IN TECHNICAL DATA—NONCOMMERCIAL ITEMS. (NOV 1995)

(a) Definitions. As used in this clause:

(1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.

(2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

(4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

(5) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.

(6) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.

(7) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.

(i) Private expense determinations should be made at the lowest practicable level.

(ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.

(8) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.

(9) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

(10) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(11) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(12) Government purpose rights means the rights to—

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.

(13) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release or disclose such data or authorize the use or reproduction of the data by persons outside the Government if reproduction, release, disclosure, or use is —

(i) Necessary for emergency repair and overhaul; or

(ii) A release or disclosure of technical data (other than detailed manufacturing or process data) to, or use of such data by, a foreign government that is in the interest of the Government and is required for evaluational or informational purposes;

(iii) Subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and

(iv) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.

(14) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

(15) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

(b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):

(1) Unlimited rights.

The Government shall have unlimited rights in technical data that are—

(i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;

(ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;

(iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;

(iv) Form, fit, and function data;

(v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);

(vi) Corrections or changes to technical data furnished to the Contractor by the Government;

(vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;

(viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or

(ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with —

(A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or

(B) Government purpose rights and the Contractor’s exclusive right to use such data for commercial purposes has expired.

(2) Government purpose rights.

(i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data—

(A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs (b)(ii) and (b)(iv) through (b)(ix) of this clause; or

(B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.

(iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-

(A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or

(B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.

(iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.

(3) Limited rights.

(i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data—

(A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or

(B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.

(ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.

(iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.

(4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(13) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless—

(i) The parties have agreed otherwise; or

(ii) Any restrictions on the Government’s rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

(6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(13) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

(c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.

(d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.

(e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.

(2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.

(3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted

to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted—

Technical data to be Furnished With Restrictions (1)	Basis for Assertion (2)	Asserted Rights Category (3)	Name of Person Asserting Restrictions (4)
(LIST)	(LIST)	(LIST)	(LIST)

(1) If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

(2) Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or

disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

(3) Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

(4) Corporation, individual, or other person, as appropriate.

Date _____

Printed Name and Title _____

_____

Signature _____

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:

Government Purpose Rights

Contract No.

Contractor Name

Contractor Address

Expiration Date

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical Data—Noncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:

Limited Rights

Contract No.

Contractor Name

Contractor Address

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in ,Technical Data—Noncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.

(End of legend)

(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:

Special License Rights

The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No. (Insert contract number) , License No. (Insert license identifier) . Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.

(End of legend)

(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b)(5) of this clause).

(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

(g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliers that will deliver technical data with other than unlimited rights, shall—

(1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and

(2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.

(h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.

(2) Nonconforming technical data markings. A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.

(i) Relation to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.

(j) Limitation on charges for rights in technical data. (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when—

(i) The Government has acquired, by any means, the same or greater rights in the data; or

(ii) The data are available to the public without restrictions.

(2) The limitation in paragraph (j)(1) of this clause—

(i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and

(ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.

(k) Applicability to subcontractors or suppliers. (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.

(2) Whenever any technical data for noncommercial items is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, and require its subcontractors or suppliers to do so,

without alteration, except to identify the parties. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

(3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.

(4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

252.227-9000 COMPUTER CODE DEVELOPMENT (OCT 1998)

Computer code development (the writing of a new computer program or the enhancement of an existing program to expand its capabilities) even if not explicitly specified in the Tasks of the SOW, shall be accompanied by a report which will be a brief summary describing the software, associated machine requirements and development and documentation status of each Computer Code for DTRA to determine the applicability of the Computer program to specific research programs.

252.235-9000 SOURCES OF INFORMATION (JULY 2000)

a. The results of the research to be delivered to the Government under this Contract shall embody the most recent reliable information in the field which is available to the Contractor from private and governmental sources, and the Contractor agrees to utilize all sources of such information available to it. In this connection, information in this field which is in the control of DTRA shall, with the consent of the Contracting Officer's Representative (COR) and under such safeguards and procedures as he/she may prescribe, be made available to the Contractor on request. Additionally, the Contractor is encouraged to make use of the resources available through the Defense Threat Reduction Information Analysis Center (DTRIAC), 1680 Texas Street, Southeast, Kirtland AFB, New Mexico 87117.

b. Reasonable assistance in obtaining access to information, or in obtaining permission to use Government or private facilities, will be given to the Contractor by DTRA. Specifically, the Contractor must register with the Defense Technical Information Center, ATTN: DTIC, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060-6218, in accordance with Defense Logistics Agency (DLA) Regulation 4185.10, Certification and Registration for Access to DoD Defense Technical Information. DD Form 1540, the registration form, shall be forwarded to the DTRA Contracting Officer for approval (DFARS 35.010(b)).

(End of clause)

252.227-9000 PROHIBITION OF USE OF LABORATORY ANIMALS (OCT 2008)(DTRA)

No animal studies may be conducted using DOD funds until Animal Care and Use Review Office (ACURO) approval has been granted. Studies involving non human primates, dogs, cats, or marine mammals will require a site visit by a DoD laboratory animal veterinarian. The recipient (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO). You must complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: https://mrmc-www.army.mil/AnimalAppendix.asp.

Please submit the completed ACURO appendix, contact information, the DTRA contract number and a copy of the contract for processing to the email address listed at the ACURO website for processing. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army MRMC ACURO under separate email to the recipient and Principal Investigator. A copy of this approval will be provided to the Defense Threat Reduction Agency (DTRA) for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

(End of Clause)

252.235-9001 PROHIBITION OF USE OF LABORATORY ANIMALS (OCT 2008)(DTRA)

No animal studies may be conducted using DOD funds until Animal Care and Use Review Office (ACURO) approval has been granted. Studies involving non human primates, dogs, cats, or marine mammals will require a site visit by a DoD laboratory animal veterinarian. The recipient (including subcontractors) is expressly forbidden to use laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Material Command (MRMC), Animal Care and Use Review Office (ACURO). You must complete the ACURO Animal Use Appendix for Research Involving Animals found at the following web site: https://mrmc-www.army.mil/AnimalAppendix.asp. Please submit the completed ACURO appendix, contact information, the DTRA contract number and a copy of the contract for processing to the email address listed at the ACURO website for processing. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army MRMC ACURO under separate email to the recipient and Principal Investigator. A copy of this approval will be provided to the Defense Threat Reduction Agency (DTRA) for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

252.242-9000 CONTRACTOR PERFORMANCE ASSESSMENT REPORTING SYSTEM (CPARS) (NOV 2002)

1. As required by FAR Parts 42 and 15, and DTRA policy for the Contractor Performance Assessment Reporting System (CPARS) and Past Performance Information Retrieval System (PPIRS), formerly known as PPAIS, effective July, 2001, the Government shall complete a CPAR each year of the period of performance of this contract. The contractor will have an opportunity to provide their comments in each CPAR before it is completed. In accordance with DTRA CPARS policy the completed CPARs will be entered into PPIRS, a retrieval system for Government source selection teams to access the CPARs of contractor's performance. The DTRA CPARS and PPIRS policy includes an explanation of the process and procedures that will be utilized under this contract. A copy is available for contractor reference via the DTRAlink (www.dtra.mil) by accessing Acquisition, Doing Business With Us.

2. The CPARs shall occur annually in accordance with the schedule established below:

(i) Initial CPAR: 12 months after contract start date (date performance begins) TBD (by PCO)

(ii) Interim CPAR(s) will be performed annually on the anniversary of the contract start date according to the following schedule: TBD (by PCO)

(iii) A Final CPAR will be completed upon contract termination, transfer of program management/contract management responsibility outside of DTRA, the delivery of the final end item on contract and/or the completion of the performance period.

(iv) An Out-of-Cycle CPAR may be required when there is a significant change in performance that alters the assessment in one or more evaluation area(s). An Out-of-Cycle CPAR is optional and shall be processed in accordance with DTRA CPARS policy referenced in paragraph 1. above.

3. Each CPAR shall only cover the period elapsing from the last annual CPAR. The final CPAR shall not be used to summarize or "roll-up" the contractor's performance under the entire contract. Each annual CPAR and the final CPAR together will comprise a total picture of contractor performance.

4. At the request of the Government, a verbal, informal review of the Contractor's performance may be held 3-6 months before the completion of the Interim or Final Evaluation periods. This review entails discussing any problems or areas of concern regarding the Contractor's performance to date. No written evaluation form or other formal documentation is required for this evaluation. It may be conducted with the Contractor by telephone, teleconference or face-to-face. This is designed to offer the Contractor an opportunity to correct known deficiencies or weaknesses prior to the formal written evaluation.

5. As set forth in DTRA CPARS policy, any disagreements between the Contractor and the Program Manager regarding the CPAR(s) that cannot be resolved shall be reviewed by the designated Reviewing Official prior to completion of the CPAR.

6. Special Requirements for Indefinite Delivery Contracts (IDIQ and Requirements type), CPARs shall be processed (select one)

o for all existing orders (combined) at the time the CPAR is processed

o on an order-by-order basis

o on a grouped order basis

7. The policy and procedures set forth in this clause and DTRA CPARS policy are not subject to "Disputes" as described in FAR Part 33.

252.245-9000 Government Property (AUG 2009)

(a) In accordance with FAR 52.245-1(b), Property Management, and FAR 52.245-1(f), Contractor Plans and Systems, the Contractor shall have a system to manage (control, use, preserve, protect, repair and maintain) Government property in its possession.

(b) The Contract Data Requirements Lists (CDRLs) associated with the Property for this Contract are contained in Exhibit "A" and included in Section J of this contract. The spreadsheet required by the CDRL entitled "Master Government Property List (MGPL) will be incorporated in Section J of this contract.

(c) The Contractor shall provide to the Government an updated MGPL according to the CDRL.

(d) The Government Site Visits/Physical Inventory — The DTRA will annually verify the Property in the Possession of the Contractor. The Contactor's Point of Contact shall coordinate with the Program Manager/Contracting Officer Representative or DTRA Accountable Property Officer (APO) on prearranged site visits upon request.

(e) The Contractor shall annually conduct and provide to the DTRA a physical inventory report of ALL Government Property in its possession according to the Master Government Property List (Physical Inventory) CDRL.

(f) The physical inventory report shall be validated/confirmed via signature by both the Contractor's Property Administrator and the DTRA's Government Representative (i.e. COR, APO, etc.). Inventory discrepancies must be reported immediately to the Contracting Officer, COR/Program Manager and resolved by the DTRA APO.

(g) The Contractor shall provide all CDRL reports to the Government electronically in a spreadsheet using Microsoft Office Excel. Unless otherwise specified, the contractor shall submit all data through the IUID Registry.

(End of Clause)

Section J - List of Documents, Exhibits and Other Attachments

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	CLIN 0002 Exhibit(s)	1	
Attachment 1	Statement of Work	11	15-MAR-2009
Attachment 2	CDRLS	5	15-SEP-2009

Statement of Work
03/15/09

1.0 OBJECTIVE

Brief Overview of Specialty Area: Our proposal addresses the topic: Protect the Department of Defense from WMD. We will attempt to develop new and improve existing antiviral vaccines to immunize the warfighter against often debilitating or lethal viral diseases. Our vaccine formulation will encode antigens from viral biothreat agents (e.g., Rift Valley fever virus (RVFV)) and will lead to a strong adaptive immune response against the targeted pathogens. These pre-treatments will also have utility for the general public in regions where the target pathogens are endemic or emerging, even in the United States where the spread of RVFV would rival that of West Nile virus.

Why Work is Being Pursued: Viral infections present a significant threat to our troops abroad, to the United States mainland as a potential bioweapon, and to travelers and indigenous populations where the pathogens are endemic and/or emerging. Many viral agents are classified as NIAID Category A Priority Pathogens and as Biosafety Level (BSL-) 3 or 4 agents due to the lack of available vaccines and/or their case of dissemination by aerosol transmission. The initial focus will be to combine the broadly applicable aGal Adjuvant Technology with vaccine candidates against RVFV. This pathogen is a real and common threat. The lack of prophylactic and therapeutic measures, the potential for human-to-human transmission, and the significant threat to livestock associated with RVFV, make infection with these pathogens a serious public health concern not only in endemic, developing countries, but also in many non-endemic developed countries due to the recent bioterror threats. Until recently RVFV outbreaks had been limited to the African continent. However, the geographical range of RVFV has now expanded, with outbreaks in Saudi Arabia and Yemen in 2000 affecting both livestock and humans. More recent reports of infected livestock within Russia, Afghanistan and Northern India have been confirmed [77]. This is a clear indication that RVFV is not solely an African disease but a geographically rapidly expanding disease which is quickly becoming a threat to the US. Importantly, the number of outbreaks and lethality of these outbreaks have not lessened over time, and there are indications that they may have become more severe. The urgent need for an effective vaccine for RVFV is illustrated by the statistics from recent outbreaks: From 13th Jan to 3rd May 2007, a total of 264 cases including 109 deaths [case fatality ratio *(CFR) 41%*] of RVF were reported in Tanzania-; from 30th Nov 2006 to 12th Mar 2007, a total of 684 cases including 155 deaths *(CFR 23%)* of RVF were reported in Kenya. From 19th Dec 2006 to 20th Feb 2007, a total of 114 cases including 51 deaths *(CFR 45%)* of RVF were reported in Somalia [World Health Organization (WHO), CSR, Disease Outbreak News, Wed 9 May 2007]. Although the mortality rate for humans infected with RVFV previously reported was less than 2%, it is clear that the mortality rate in these recent outbreaks is substantially higher. Although not addressed by these reports, it is likely that morbidity is also substantially increased.

What We are Trying to Accomplish: We will attempt to demonstrate the broad applicability of the aGal Adjuvant Technology to any existing or new antiviral vaccine platform to protect the warfighter from potentially lethal infection. These modified,

improved vaccines against primarily viral pathogens identified as priority threats by the DoD will also be useful for the general population in areas where human pathogenic viral agents are endemic or emerging, as well as in the event of a suspected bioterror incident.

Overall, this proposed project will illustrate how the broad-spectrum aGal Adjuvant Technology will improve the efficacy of new and existing vaccines, which should lead to a reduction in the overall number of required vaccinations and a decrease of the vaccine dose, thus making vaccine production more cost-effective and for the end user (i.e., government: Strategic National Stockpile and National Veterinary Stockpile) more affordable.

2.0 SCOPE: This proposal, "aGal Adjuvant Technology for Biodefense Agents", is in support of the R&D Innovation Office (RD-INO).

Goals: This effort will support the DTRA campaign, "Protect the Department of Defense from WMD", aimed at developing Protection and Mitigation technologies, methodologies, and/or standards for eventual transition through the DTRA R&D Enterprise.

[*]

3.0 BACKGROUND

aGal Adjuvant Technology: Safety and Broad Applicability: The purpose of an adjuvant is to stimulate the immune system to respond more strongly to an antigen than it normally would. A very good adjuvant can mean that a fraction of the antigen can be used to stimulate the body's defense to create immunity to a disease. Since the antigen is the most expensive and difficult component required for the production of an effective vaccine, good adjuvants can be the key to generate any functional vaccine.

The aGal Adjuvant Technology exploits a robust zoonotic blockade against viruses from lower animals to enhance potency of antiviral vaccines. Human naturally acquired immunity against the common aGal epitope (galactose-alpha(1,3)-galactose-beta(1,4)N-acetyl-glucosamine-R (Gal-a(1-3)-Gal-b(1.4)-GlcNAc-R) is facilitated by the loss of a key enzyme in the epitope's biosynthetic pathway. Since human cells are devoid of this epitope, chronic stimulus from gut flora leads to high levels of circulating anti-aGal Abs (IgG and IgM) and the development of a robust immune response pathway. Because the aGal epitope is immediately recognized as foreign, the naturally acquired aGal immune pathway in humans serves as a strong barrier to zoonotic infection. The aGal Adjuvant Technology takes advantage of this natural process to facilitate the rapid presentation of modified antigens to antigen-presenting cells, leading to a strong immune response. The evolutionary immunity to aGal ensures that the presence of aGal epitopes on antigens will lead to a robust immune response involving cross-activation of T_H1 immunity, characterized by cytokine secretion and increased phagocytic activity, and T_H2 immunity characterized by high Abs titers. Interestingly, birds are also a1,3 GT-negative and this might explain why several pathogens transmitted by birds have readily jumped to humans (avian flu H5N1, West Nile virus, Eastern equine encephalitis).

Ab titers against aGal epitopes are among the highest recorded in humans and can comprise >2% of the entire circulating Ab repertoire. These Abs are also responsible for the well-documented immunologic phenomenon known as hyperacute rejection (of $aGal^{(+)}$ tissues), experimentally observed during attempts at xenotransplantation.

[*]

Product Management Plan: The PI Dr. Link and the Program Manager Dr. Flick shall update the Product Development Plan within thirty (30) calendar days of the effective date of the contract. The contractor shall obtain approval of the Project Officer and Contracting Officer prior to the initiation of any activities related to its execution. Dr. Link shall oversee the performance of all activities based on the approved Implementation Plan. Both the PDP and Implementation Plan will be reviewed at a Post-Award Contract Initiation Meeting planned and coordinated by Dr. Link and shall include the PI, Project Manager, key investigators, and appropriate key contractor and subcontractor personnel, Project Officer, other DTRA and DoD staff designated by the Project Officer and the Contracting Officer. Dr. Flick and Dr. Link will provide oversight on the performance of all activities based on defined milestones and timelines approved by the Project Officer and the Contracting Officer. In addition, the PI and Program Manager will be responsible for the development of, review and recommendations for all proceed (Go/No Go) decision points throughout the period of performance, including listing quantitative and qualitative assessment criteria, both scientific and regulatory, for advancing the candidate vaccine past each Go/No Go decision point to the next stage of product development for all Research and Development Activities. In addition, they will be responsible for annual updates and any change in milestones. The contractor shall obtain approval of the Project Officer and the Contracting Officer of all updates and changes to the PDP prior to the initiation of any activities related to its execution. The contractor shall provide a detailed timeline, in Gantt chart format with predecessor and successor logic, covering the initiation, conduct and completion of each product development task that is linked to direct costs for each product development milestone identified in the PDP. Dr. Link will elicit input and recommendations as needed from all team member designees in developing the PDP, timelines, and management decisions. The PI shall submit all required reports (i.e., Quarterly Contract Performance Report, Cumulative Annual Progress Report, etc.) as defined in the Contract Data Requirement List (CDRL).

[*]

Procedures to handle adverse experimental or production developments: The occurrence of adverse experimental data or production difficulties is fairly common in biologics development and manufacturing. The responsibility of every individual in the project is to address these problems in a constructive manner. Supervisory personnel, whether in the research laboratory or operating in QA/QC, will convey written notice of such problems or concerns to the project manager (or their designee) in a timely fashion. It is the responsibility of the project manager to convene a meeting of stakeholders in the affected processes to allow discussion of issues. These meetings

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will he recorded such that proposals that further define and/or resolve those problems are acted upon in a timely fashion. The Principal Investigator is responsible for determining whether satisfactory resolution has been achieved. If developments are such that the project goals are jeopardized or require actions outside the scope of the contract, the PI is required to assure notification of the Project Officer in a timely manner so that alternative strategies and/or remedial actions may be taken.

[*]

CONTRACT DATA REQUIREMENTS LIST

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
N/A	A	TDP ____ TM ____ OTHER ____

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Chemical/Biological Medical Systems		BioProtection Systems Corporation

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A001	Quarterly Status Report	Quarterly Contract Performance Report

4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
N/A	N/A	DTRA/CBM

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	N/A	Quarterly	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16. REMARKS
Blocks II - 13: First report due within 15 days after end of first Fiscal Quarter after award. Subsequent reports due within 15 days after end of each FQ. Format as provided to the contractor.

14. DISTRIBUTION	b. COPIES		
a. ADDRESSEE	Draft	Final Reg	Final Repro
DTRA/CBM		1	
DTRA/BCR		1	
DTRA/COR		1	
15. TOTAL →	0	3	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A002	Annual Report	Cumulative Annual Progress Report

4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
N/A	N/A	DTRA/CBM

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	N/A	See Blk. 16	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16/. REMARKS
Blocks 10-13: First submission within 15 days after the end of the first Fiscal Year following award. Subsequent reports due within 15 days after the end of the Fiscal Year. Format as provided to the contractor.

14. DISTRIBUTION	b. COPIES		
a. ADDRESSEE	Draft	Final Reg	Final Repro
DTRA/CBM		1	
DTRA/BCR		1	
DTRA/COR		1	
15. TOTAL →	0	3	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A003	Quarterly Financial Status Report	

4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
N/A	N/A	DTRA/CBM

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	N/A	Quarterly	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16. REMARKS
Blocks 11 - 13: First report due within 15 days after end of first Fiscal Quarter after award. Subsequent reports due within 15 days after end of each FQ. Format as provided to the contractor.

14. DISTRIBUTION	b. COPIES		
a. ADDRESSEE	Draft	Final Reg	Final Repro
DTRA/CBM		1	
DRA/BCR		1	
DTRA/COR		1	
15. TOTAL →	0	3	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE

4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
N/A	N/A	

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
	N/A		
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**

16. REMARKS

14. DISTRIBUTION	b. COPIES		
a. ADDRESSEE	Draft	Final Reg	Final Repro
15. TOTAL →	0	0	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
/s/William Dowling	8/13/08	/s/ Paula R. Bryant	9/24 03

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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0189

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
002	A	TDP _____ TM _____ OTHER _____

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Alphagal Adj Tech for biodefense	TBD	BioProtection Systems Corp

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A004	Expenditure Forecast	Project Spend Plan

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DU-MGMT-81468	N/A	DTRA-RD-CBM

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	See Blk 16	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16. REMARKS

1. Submission shall be furnished electronically via e-mail in contractor format.
2. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14.
3. First submission within 30 days of contract award. Updates to be made annually.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
DTRA-RD-CBM	0	1	0
DTRA-BE-BCR	0	1	0
15. TOTAL ⟶	0	2	0

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A005	Patents – Reporting of subject inventions	N/A

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MISC-80711A	SOW	DTRA-RD-CBM

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	See Blk. 16	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16/. REMARKS

1. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14.
2. Provide copies of invention disclosures for subject inventions within 2 months of an employee inventor reporting a subject invention to the Contractor.
3. Report all subject inventions on DD Form 882 every 12 months from the date of the contract award.
4. Report all subject inventions on DD Form 882 in a final report.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
DTRA-RD-CBM	1	1	0
DTRA-BE-BCR	0	1	0
15. TOTAL ⟶	1	2	0

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
/s/William Dowling	9/15/09	/s/William Dowling	9-15-09

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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY:
002	A	TDP _____ TM _____ OTHER _____

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Alphagal adj tech for biodefense	TBD	BioProtection Systems Corp

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A006	Regulatory approval and technical data packages	Submission Report (Regulatory Appr. Docs)

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
NA	NA	DTRA-RD-CBM

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	See Blk 16	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16. REMARKS

1. Submission shall be furnished electronically via e-mail in contractor format.
2. See attached addressee sheet for a listing of e-mail and postal addresses for the individuals listed in Block 14.
3. The contractor will provide the Government copies of all technical data generated by the company prior to or during the performance of this contract that would be necessary to pursue FDA approval of an investigational new drug, a new drug application, biologics license application or other approval and notify the Government of FDA decisions.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
DTRA-RD-CBM	0	1	0
DTRA-BE-BCR	0	1	0
15. TOTAL ⟶	0	2	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A007	Miscellaneous data submissions	None

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
N/A	N/A	DTRA-RD-CBM

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	1 time	See Blk. 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Blk. 16	See Blk. 16

16/. REMARKS

Submission frequencies and dates will be dictated in the SOW tasks. Deliverable shall be compatible electronic media. Contractor format acceptable, unless specifically cited in SOW.

14. DISTRIBUTION

a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
DTRA-RD-CBM	0	1	0
DTRA-BE-BCR	0	1	0
15. TOTAL ⟶	0	2	0

17. PRICE GROUP

18. ESTIMATED TOTAL PRICE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
William Dowling /s/William Dowling	9/15/09	William Dowling /s/William Dowling	9/15/09

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CONTRACT DATA REQUIREMENTS LIST (1 Data Items)				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports. 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget. Paperwork Reduction Project (0704-0188), Washington, DC 20503. Please DO NOT RETURN your form to either of these addresses. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.					
A. CONTRACT LINE ITEM NO. 002	B. EXHIBIT A	C. CATEGORY: TDP TM OTHER			
D. SYSTEM/ITEM Alphagal adj tech for biodefense	E. CONTRACT/PR NO. TBD	F. CONTRACTOR BioProtection Systems Corp			
1. DATA ITEM NO. A008	2. TITLE OF DATA ITEM Master Government Property List	3. SUBTITLE GFP, GFE, GFM, and Contractor Acquired Property)			
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80269	5. CONTRACT REFERENCE SOW PARA	6. REQUIRING OFFICE DTRA/BE-BL			
7. DO 250 REQ LT	9. DIST STATEMENT REQUIRED N/A	10. FREQUENCY See Block 16	12. DATE OF FIRST SUBMISSION See Block 16	14. DISTRIBUTION	
8. APP CODE A		11. AS OF DATE See Block 16	13. DATE OF SUBSEQUENT SUBMISSION See Block 16		

16. REMARKS

BLOCK 4: This DID is for reference only. The report shall be prepared according to the remarks below.
BLOCK 10: Monthly
BLOCK 11: Award of Contract/Task Order
BLOCK 12: 45th calendar day following Contract/Task Order award
BLOCK 13: Tenth calendar day of each month

Remarks: During performance of the Contract, the Contractor may purchase material or equipment using government Funds [Contractor Acquired Property (CAP)] if approved by Contract Officer. The Contractor shall provide a Master Government Property List (MGPL), inclusive of all CAP, on the 45th calendar day following Contract/Task Order award and the tenth calendar day of each subsequent month.

The Mater Government Property List shall include all equipment/property provided to the contract, including equipment transferred between projects, broken and obsolete equipment, and items purchased outside the United States. The Master Government Property List shall consist of the following data elements at a minimum: Accountable Contract/Task Order Number, Original Manufacturer's Name Noun Name Description/Commercial Use, Original Manufacturer's Part Number, Model Number, Serial Number, DTRA Asset ID #, Equipment Identification Number Quantity, Task Order to which equipment in assigned, Work Breakdown Schedule (WBS) Project Number, Item Unique Identifier or equivalent, Project Descriptor, Equipment Location, Data Placed in Service, Condition of Property, Status (active, stored, in-transit or waiting disposal), Government Property Type [Government Furnished Equipment (GFE), Government Furnished Material (GFM), Government Furnished Property (GFP), Contractor Acquired Property (CAP)]. Unit Acquisition Cost (From Accounting System) and Remarks.

The Master Government Property List shall be delivered electronically in a spreadsheet using Microsoft Office Excel. Abbreviations are not allowed.

Ninety (90) days prior to Contract expiration, the Contractor shall submit a final Master Government Equipment List suitable for close-out purposes containing use/disposition recommendations.

a. ADDRESSEE	b. COPIES Draft	Final Reg	Final Repro
DTRA/BE-BL		1	
DTRA/BE-BF		1	
DTRA/BE-BI		1	
DTRA/BE-BC		1	
DTRA/COR		1	
15. TOTAL ▶	0	5	0

17. PRICE GROUP	
18. ESTIMATED TOTAL PRICE	

G. PREPARED BY William Dowling	H. DATE 9/15/09	I. APPROVED BY William Dowling	J. DATE 9/15/09
/s/ William Dowling		/s/ William Dowling	

DD FORM 1423-1, JUN 90 (EG) PREVIOUS EDITION ARE OBSOLETE Page 1 of 1 Pages

BE-BC SOP 09-03 Enclosure

CONTRACT DATA REQUIREMENTS LIST (1 Data Items)				Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. Please DO NOT RETURN your form to either of these addresses. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY: TDP TM OTHER	
002	A		

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
Alphagal adj tech for biodefense	TBD	BioProtection Systems Corporation

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A009	Master Government Property – Physical Inventory	GFP, GFE, GFM, and Contractor Acquired Property)

4. AUTHORITY (Data Acquisition Document No.)	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-80441	SOW PARA	DTRA/BE-BL

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	N/A	See Block 16	See Block 16
8. APP CODE		**11. AS OF DATE**	**13. DATE OF SUBSEQUENT SUBMISSION**
A		See Block 16	See Block 16

16. REMARKS

BLOCK 4: This DID is for reference only. The report shall be prepared according to the remarks below.
BLOCK 10: Annually
BLOCK 11: Award of Contract/Task Order
BLOCK 12: 1 Month after Contract/Task Order Award
BLOCK 13: Annually

Remarks: The Contractor shall annually perform, record and disclose physical inventory results of all Contractor Acquired Property in the Contractor's possession. This report shall include ALL Government Property/Contractor Acquired Property/Equipment/Material. A final coordinated physical inventory shall be performed upon contract completion or termination and approved by the DTRA Accountable Property Officer.

The physical inventory report shall indentify the Contractor's Point of Contact with telephone number and signature and the following data elements at a minimum: Accountable Contract/Task Order Number, Original Manufacturer's Name, Description/Commercial Use, Original Manufacturer's Part Number, Model Number, Serial Number, DTRA Asset ID #, Equipment Identification Number, Quantity, Task Order to which equipment in assigned, Work Breakdown Schedule (WBS) Project Number, Item Unique Identifier or equivalent, Project Descriptor, Equipment Location, Data Placed in Service, Condition of Property, Status (active, stored, in-transit or waiting disposal), Government Property Type [Government Furnished Equipment (GFE), Government Furnished Material (GFM), Government Furnished Property (GFP), Contractor Acquired Property (CAP)]. Unit Acquisition Cost (From Accounting System) and Remarks.

The physical inventory report shall be documented in writing and validated/confirmed, via signature, by both the Contractor's Property Administrator and the DTRA's Governmental Representative. Inventory discrepancies must be reported immediately to the Contracting Officer, Contracting Officer Representative/Program Manager or DTRA Accountable Property Officer. The report shall contain original signatures with spreadsheet attachments and be delivered electronically in a spreadsheet using Microsoft Office Excel. Abbreviations are not allowed.

Ninety (90) days prior to Contract expiration, the Contractor shall submit a final property identification listing suitable for close-out purposes containing use/disposition recommendations. The report must be reviewed, approved and signed by the DTRA Accountable Property Officer prior to contract close out.

14. DISTRIBUTION			
a. ADDRESSEE	b. COPIES		
	Draft	Final	
		Reg	Repro
DTRA/BE-BL		1	
DTRA/BE-BF		1	
DTRA/BE-BI		1	
DTRA/BE-BC		1	
DTRA/COR		1	
15. TOTAL ⟶	0	5	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY William Dowling	H. DATE 09/15/09	I. APPROVED BY William Dowling	J. DATE 09/15/09
/s/ William Dowling		/s/ William Dowling	

DD FORM 1423-1, JUN 90 (EG) PREVIOUS EDITION ARE OBSOLETE Page 1 of 1 Pages

BE-BC SOP 09-03 Enclosure

Exhibit 10.79

AMENDMENT #8

To Letter of Intent for Proposed CRADA #02166

"Preclinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent"

The purpose of this amendment is to change certain terms of the Letter of Intent (LOI) for the proposed Cooperative Research and Development Agreement (CRADA) entitled "Preclinical and Clinical Development of 1-Methyl-[d]-Tryptophan as an Anti-Cancer Agent". These changes are reflected below, and except for these changes, all other provisions of the original CRADA LOI remain in full force and effect. Two originals of this amendment are provided for execution; one is to remain with the National Cancer Institute (NCI) and the other copy is to remain with the Collaborator.

Upon final signature, the term of the CRADA Letter of Intent is retroactively extended for one year from May 23, 2011 to, May 23, 2012.

AGREED AND ACCEPTED:

For the National Cancer Instute:

/s/ Douglas R. Lowy, M.D.	5/26/2011
Douglas R. Lowy, M.D. Deputy Director, NCI	Date

For NewLink Genetics Corporation:

/s/ Nicholas Vahanian, M.D.	6/2/2011
Nicholas Vahanian, M.D. Chief Operating Officer	Date

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE: U	PAGE 1 OF PAGES 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
	20-Sep-2011	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
HDTRA1		S2401A	

DEFENSE THREAT REDUCTION AGENCY/BDJ
8725 JOHN J. KINGMAN MS 6201
FT BELVOIR VA

DCMA TWIN CITIES
B. H. WHIPPLE FEDERAL BLDG. RM 150
FT. SNELLING MN 55111

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)		9A. AMENDMENT OF SOLICITATION NO
BIOPROTECTION SYSTEMS CORPORATION DR. CHARLES LINK 2801 S LOOP DR STE 3360 AMES IA 50010-6648		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. HDTRA1-09-C-0014
CODE 47EJ3 / FACILITY CODE	X	10B. DATED (SEE ITEM 13) 25-Sep-2009

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing items 8 and 15, and returning _____copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR CLAUSE 52.243-5 Alt II, Changes-Cost Reimbursement
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: authierr112327

The purpose of this modification is to make an in-scope change to the SOW based on the new congressional funding profile and the development of the contractor's alpha-gal technology. The revision to the SOW and CLIN 0001 removes the requirement to include an option for this contract. Therefore, CLIN 0003 and the option is hereby removed/deleted. All other terms and conditions remain the same.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Carl Langren, VP Finance		Victor E. Cramer, Contracting Officer TEL: EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Carl Langren (Signature of person authorized to sign)	9/21/2011	BY /s/ Victor E. Cramer (Signature of Contracting Officer)	9/21/2011

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $3,388,914.00 from $3,707,837.00 to $7,096,751.00.
The effective date has changed from 25-Sep-2009 to 19-Sep-2011.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The estimated/max cost has increased by $3,165,814.00 from $3,408,767.00 to $6,574,581.00.
The fixed fee has increased by $223,100.00 from $299,070.00 to $522,170.00.
The total cost of this line item has increased by $3,388,914.00 from $3,707,837.00 to $7,096,751.00.

CLIN 0003

The CLIN type priced has been deleted.
The CLIN description has changed from Option Year One to Deleted.
The CLIN extended description Option Year Deleted based on Modification P0001 has been added.
The estimated/max cost has decreased by $6,705,742,00 from $6,705,742.00 to $0.00.
The fixed fee has decreased by $186,042.00 from $186,042.00 to $0.00.
The option status has changed from Option to No Status.
The total cost of this line item has decreased by $6,891,784.00 from $6,891,784.00 to $0.00.

SUBCLIN 000103 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103					$ 0.00
	Base Period Funding				
	CPFF				
	FOB: Destination				
				ESTIMATED COST	$ 0.00
				FIXED FEE	$ 0.00
				TOTAL EST COST + FEE	$ 0.00
	ACRN AC				$ 3,388,914.00
	CBM119922294000104				

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000103:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 25-SEP-2009 TO 24-SEP-2011	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 25-SEP-2009 TO 24-SEP-2013	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 25-SEP-2009 TO 24-SEP-2012	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC

POP 25-SEP-2009 TO 24-SEP-2013	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1

The following Delivery Schedule Item has been deleted from CLIN 0003:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
POP 25-SEP-2011 TO 24-SEP-2012	N/A	DEFENSE THREAT REDUCTION AGENCY/RD-CBM SEE SEPARATE LETTER 8725 JOHN J KINGMAN ROAD, MAIL STOP 6201, FORT BELVOIR VA 22060 FOB: Destination	HDTRA1

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $3,388,914.00 from $3,707,837.00 to $7,096,751.00.

SUBCLIN 000103:
Funding on SUBCLIN 000103 is initiated as follows:

ACRN: AC

CIN: CBM119922294000104

Acctng Data: 9700400.2620 1000 B62D 255999 BD36082000 549012 DODAAC: 1-01115

Increase: $3,388,914.00

Total: $3,388,914.00

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The Table of Contents has changed from:

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	CLIN 0002 Exhibit(s)	1	
Attachment 1	Statement of Work	11	15-MAR-2009
Attachment 2	CDRLS	5	15-SEP-2009

to:

Exhibit/Attachment Table of Contents

DOCUMENT TYPE	DESCRIPTION	PAGES	DATE
Exhibit A	CLIN 0002 Exhibit(s)	1	
Attachment 1	Statement of Work	18	15-Aug-2011
Attachment 2	CDRLS	5	15-SEP-2009

(End of Summary of Changes)

Notice of Award

SMALL BUSINESS INNOVATION RESEARCH PROG **Issue Date:** 03/24/2011
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R43AI084350-02

Principal Investigator(s):
Ramon Flick, PhD

Project Title: Development of Multivalent Vaccines Against Yellow Fever and Arena Viruses

Marilyn Moehlmann
BioProtection Systems Corporation 2901 South Loop Drive
Suite 3360
Ames, IA 50010

Award e-mailed to: clangren@bpsys.net

Budget Period: 04/01/2011 — 03/31/2012
Project Period: 04/06/2010 — 03/31/2012

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $299,920 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to BIOPROTECTION SYSTEMS CORPORATION in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as "The project described was supported by Award Number R43AI084350 from the National Institute Of Allergy And Infectious Diseases. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Allergy And Infectious Diseases or the National Institutes of Health."

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an Investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator's spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Dawn M. Mitchum
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I — AWARD DATA — 5R43AI084350-02

Award Calculation (U.S. Dollars)		
Salaries and Wages	$	81,840
Fringe Benefits	$	14,485
Personnel Costs (Subtotal)	$	96,325
Consultant Services	$	5,500
Supplies	$	31,000
Travel Costs	$	3,550
Other Costs	$	19,100
Consortium/Contractual Cost	$	25,796
Federal Direct Costs	$	181,271
Federal F&A Costs	$	113,030
Approved Budget	$	294,301
Fee	$	5,619
Federal Share	$	299,920
TOTAL FEDERAL AWARD AMOUNT	$	299,920
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$	299,920

SUMMARY TOTALS FOR ALL YEARS

YR	THIS AWARD	CUMULATIVE TOTALS
2	$ 299,920	$ 299,920

Fiscal Information:

CFDA Number:	93.855
EIN:	1202844633A1
Document Number:	RAI084350A
Fiscal Year:	2011

IC	CAN	2011
AI	8477153	$ 299,920

NIH Administrative Data:
PCC: M32B B / **OC:** 414E / **Processed:** MITCHUMD 03/23/2011

SECTION II — PAYMENT/HOTLINE INFORMATION — 5R43AI084350-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III — TERMS AND CONDITIONS — 5R43AI084350-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. Therefore, see the NIH Grants Policy Statement Section 8.4 Closeout for closeout requirements at: http://grants.nih.gov/grants/policy/#gps.

A final Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date; see the NIH Grants Policy Statement Section 8.4.1.4 Financial Reports, http://grants.nih.gov/grants/policy/#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted through the eRA Commons (Commons) within 90 days of the expiration date.

Furthermore, unless an application for competitive renewal is submitted, a final progress report must also be submitted within 90 days of the expiration date. Institute/Centers may accept the progress report contained in competitive renewal (type 2) in lieu of a separate final progress report. Contact the awarding IC for IC-specific policy regarding acceptance of a progress report contained in a competitive renewal application in lieu of a separate final progress report.

NIH strongly encourages electronic submission of the final progress report and the final invention statement through the Closeout feature in the Commons. If the final progress report and final invention

statement are not submitted through the Commons, a copy can be emailed or sent to the contacts listed below. Copies of the HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm.

Submissions of the final progress report and HHS 568 may be e-mailed as PDF attachments to the NIH Central Closeout Center at: DeasCentralized@od.nih.gov.

Paper submissions of the final progress report and the HHS 568 may be faxed to the NIH Central Closeout Center at 301-480-2304 or mailed to the NIH Central Closeout Center at the following address:

NIH/OD/OER/DEAS
Central Closeout Center
6705 Rockledge Drive, Room 2207
Bethesda, MD 20892-7987 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)

The final progress report should include, at a minimum, a summary of progress toward the achievement of the originally stated aims, a list of significant results (positive and/or negative), a list of publications and the grant number. If human subjects were included in the research, the final progress report should also address the following:

Report on the inclusion of gender and minority study subjects (using the gender and minority Inclusion Enrollment Form as provided in the PHS 2590 and available at http://grants.nih.gov/grants/forms.htm).

Where appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see NIH Grants Policy Statement Section 4.1.15.7 Inclusion of Children as Subjects in Clinical Research at URL http://grants.nih.gov/grants/policy/#gps).

Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed.

Note, if this is the final year of a competitive segment due to the transfer of the grant to another institution, then not all the requirements stated above are applicable. Specifically a Final Progress Report is not required. However, a final FFR is required and should be submitted electronically as noted above. In addition, if not already submitted, the Final Invention Statement is required and should be sent directly the assigned Grants Management Specialist.

Treatment of Program Income:
Additional Costs

SECTION IV — AI Special Terms and Conditions — 5R43AI084350-02

FINAL PROGRESS REPORT REQUIREMENTS ? ADDITIONAL INFORMATION

In addition to the final progress report guidance provided in Section III above, please include the following in the final progress report:

There is no ?form page? for a Final Progress Report. The recommended length for the narrative portion is 10 pages.

Phase I grantees that (1) do not intend to seek Phase II support or (2) are not prepared to submit a Phase II application within four months following the expiration of the Phase I budget period, must submit a final report of their Phase I effort. Otherwise, the Phase I Final Report is a part of the Phase II application.

The format for the Final Report is as follows:

1. State the beginning and ending dates for the period covered by the (SBIR/STTR Phase I/Phase II) grant.

2. List all key personnel who have worked on the project during that period, their titles, dates of service, and number of hours devoted to the project.
3. Summarize the specific aims of the Phase I grant.
4. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Summarize the importance of the findings. Discuss any changes in the specific aims since the project was initiated. Include the Inclusion Enrollment Report with the final enrollment data for clinical research (MS Word or PDF).
5. List titles and complete references to publications, and manuscripts accepted for publication, if any, that resulted from the project?s effort. Submit five copies of such items, except patent and invention reports, as an Appendix.
6. List patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the project or describe patent status, trade secrets or other demonstration of IP protection.
7. Describe the technology developed from this SBIR/STTR, its intended use and who will use it.
8. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued).
9. If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed an IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).
10. Describe how your company has benefited from the program and/or the technology developed (e.g., firm's growth, follow-on funding, increased technical expertise, licensing agreements, spin-off companies, public offering [include stock exchange and symbol]).
11. List of the generic and/or commercial name of product, process, or service, if any, that resulted from SBIR/STTR funding. If applicable, indicate the number of products sold.
12. Provide the current number of employees (total full time equivalents [FTEs]).

INTELLECTUAL PROPERTY RIGHTS: Normally, the awardee organization retains the principal worldwide patent rights to any invention developed with United States Government support. Under Title 37 Code of Federal Regulations Part 401, the Government receives a royalty-free license for its use, reserves the right to require the patent holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States.

Rights and obligations related to inventions created or reduced to practice as a result of this award are detailed in 35 U.S.C. 205 and 37 CFR Part 401. These inventions must be reported to the Extramural Invention Reporting and Technology Resources Branch, OPERA, NIH, 6701 Rockledge Drive, MSC 7750, Bethesda, MD 20892-7750, (301) 435-1986. For additional information, access the NIH link on the Interagency Edison web site (www.iedison.gov) which includes an electronic invention reporting system, reference information and the text to 37 CFR 401.

To the extent authorized by 35 U.S.C., Section 205, the Government will not make public any information disclosing an NIH-supported invention for a 4-year period to allow the awardee organization a reasonable time to file a patent application, nor will the Government release any information that is part of that patent application.

When purchasing equipment or products under this SBIR award, the grantee shall use only American-made items, whenever possible.

The fee provided as part of this Notice of Award is in addition to direct and facilities and administrative costs. The fee is to be drawn down from the DHHS Payment Management System in increments proportionate to the draw down of costs.

Allowable costs conducted by for-profit organizations will be determined by applying the cost principles of Contracts with Commercial Organizations set forth in 48 CFR, Subpart 31.2.

The Code of Federal Regulations (Title 45 Part 74.26) stipulates that a commercial organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it expended $500,000 or more under HHS awards and at least one award is an HHS grant or subgrant. Therefore, the organization must have one grant or subgrant in order to be required to obtain a non-federal audit, but other HHS awards are included in the threshold calculations and the scope of the audit. (See threshold calculation examples, http://oamp.od.nih.gov/dfas/faqexamples.html.)

This award includes funds awarded for consortium activity with University of Texas Medical Branch. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch15.htm#_Toc271265266, pages IIB-232 -236.

Awardees who conduct research involving Select Agents (see 42 CFR 73 for the Select Agent list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens at http://www.selectagents.gov/Regulations.html) must complete registration with CDC (or APHIS, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.

Prior to conducting a restricted experiment with a Select Agent or Toxin, awardees must notify the NIAID and must request and receive approval from CDC or APHIS.

The research proposed in this grant may involve Select Agents and/or Highly Pathogenic Agents. Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving approval from the NIAID,NIH Program Official. Awardee is responsible for having its subcomponent/subcontractor comply with the requirements pertaining to the use of Select Agents and/or Highly Pathogenic Agents. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that, under some circumstances, may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm), and your Institutional Biosafety Committee (IBC) or equivalent body, or appropriate designated institutional biosafety official. If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an institutional committee or institutional official, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

· A list of the new and/or additional Agent(s) that will be studied;
· A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
· The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

For work with Select Agents performed in the U.S. provide documentation of Registration status of all domestic organizations/entities where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

Please be advised that changes in the use of a Select Agent will likely be considered a change in scope and, therefore, require NIH awarding office prior approval.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Michael J Wells
Email: wellsmj@niaid.nih.gov **Phone:** 301-451-2656 **Fax:** 301-493-0597

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SPREADSHEET SUMMARY
GRANT NUMBER: 5R43AI084350-02

INSTITUTION: BIOPROTECTION SYSTEMS CORPORATION

Budget	Year 2
Salaries and Wages	$ 81,840
Fringe Benefits	$ 14,485
Personnel Costs (Subtotal)	$ 96,325
Consultant Services	$ 5,500
Supplies	$ 31,000
Travel Costs	$ 3,550
Other Costs	$ 19,100
Consortium/Contractual Cost	$ 25,796
FEE	$ 5,619
TOTAL FEDERAL DC	$ 181,271
TOTAL FEDERAL F&A	$ 113,030
TOTAL COST	$ 299,920

Facilities and Administrative Costs	Year 2
F&A Cost Rate 1	72.7%
F&A Cost Base 1	$ 155,475
F&A Costs 1	$ 113,030

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
NewLink Genetics Corporations:

We consent to the use of our report dated February 25, 2011, except as to note 3, which is as of September 7, 2011, included herein and to the reference to our firm under the heading "Experts" in the prospectus.

Our report refers to the adoption of new guidance on the presentation and disclosure of noncontrolling interests.

KPMG LLP

Des Moines, Iowa
October 3, 2011

QuickLinks