UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the fiscal year ended December 31, 2014.

o **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**
For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION

(Exact name of Registrant as specified in Its Charter)

Delaware	**42-1491350**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

Securities registered pursuant to Section 12(b) of the Act:	**Common Stock, par value $0.01**
Name of each exchange on which registered:	**The Nasdaq Stock Market LLC**
Securities registered pursuant to Section 12(g) of the Act:	**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ☒

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company o
(Do not check if a smaller reporting company)	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant based on the closing sale price of the registrant's common stock on June 30, 2014, as reported by the NASDAQ Stock Market, was $528,615,385. Shares of the registrant's common stock beneficially owned by each executive officer and director of the registrant and by each person known by the registrant to beneficially own 10% or more of its outstanding common stock have been excluded, in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 10, 2015, there were 28,478,570 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates information by reference to our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders (the "2015 Proxy Statement").

NewLink Genetics Corporation

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K include, among other things, statements regarding the following: plans to develop and commercialize our product candidates; ongoing and planned preclinical studies and clinical trials, including the timing for completion of enrollment of one of our Phase 3 clinical trials for algenpantucel-L, and outcomes of both of our Phase 3 clinical trials for algenpantucel-L; the timing for completion of enrollment and outcomes of our other ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of any potential 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."

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. These statements involve known and unknown risks and uncertainties that may cause our, or our industry's results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among other things, those discussed under the captions "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements not specifically described above also may be found in these and other sections of this report.

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, even if new information becomes available, 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 Annual Report on Form 10-K.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. You are also advised to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, and our Current Reports on Form 8-K.

PART I

Item 1. BUSINESS

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. Our portfolio includes both biologic and small-molecule immunotherapy product candidates. Our biologic product candidates are based on our proprietary HyperAcute® immunotherapy technology, which is designed to stimulate the human immune system. Our small-molecule product candidates are focused on breaking the immune system's tolerance to cancer by inhibiting the indoleamine-(2,3)-dioxygenase, or IDO, pathway, and the tryptophan-(2.3)-dioxygenase, or TDO, pathway. We believe that our immunotherapeutic technologies have the potential to lead to multiple product candidates, targeting a wide range of oncology indications that can be used either alone or in combination with other therapies. In addition, we have licensed and are developing technologies to address infectious diseases, including our rVSV-EBOV vaccine product candidate for the Ebola virus.

Our lead product candidate, algenpantucel-L or HyperAcute Pancreas, is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. A second Phase 3 trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients. We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival. We have received Fast Track and Orphan Drug designations from the FDA and Orphan Medicinal Product designation for algenpantucel-L from the European Commission for the adjuvant treatment of patients with surgically-resected pancreatic cancer. The primary endpoint for our IMPRESS trial with algenpantucel-L for patients with surgically-resected pancreatic cancer is overall survival. As determined by the SPA, the first interim analysis was conducted when 222 deaths were reported for the study, which occurred during the first quarter of 2014. As part of this planned interim analysis, the independent data safety monitoring committee, or DSMC, met to review available patient data. As anticipated, following its review, the DSMC recommended that the study should proceed as planned, without modification. A second interim analysis is planned upon reaching 333 patient deaths, which analysis we expect to occur in the first or second quarter of 2015, and, if needed, a final analysis is planned at 444 patient deaths. Our additional HyperAcute product candidates in clinical development include tergenpumatucel-L or HyperAcute Lung, dorgenmeltucel-L or Hyper Acute Melanoma, and other potential applications. To date, our HyperAcute platform product candidates have been administered to more than 700 patients with cancer, either as a monotherapy or in combination with other treatments and have demonstrated a favorable safety profile.

Our HyperAcute immunotherapy platform consists of novel biologic products designed to stimulate the patient's immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human cancer cell lines that are tumor specific, but not patient specific. These cells have been modified to express alpha-Gal, a carbohydrate for which humans have preexisting immunity. These alpha-Gal-modified cancer cells stimulate a rapid and powerful human immune response that trains the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by "educating" the immune system to attack a patient’s own cancer cells. HyperAcute immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins. We believe these unique properties of HyperAcute products result in the stimulation of a robust immune response.

In June 2014, we entered into a Development and Manufacturing Terms and Conditions and a Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L with WuXi AppTec, Inc., or WuXi, or collectively, the WuXi Agreement. The WuXi Agreement is intended to establish a source of supply for algenpantucel-L for commercial sale, if and when that product is approved by the FDA. Under the WuXi Agreement, we granted WuXi a non-exclusive right to use certain starting materials and our confidential information to develop manufacturing processes and to manufacture cell material to be formulated into algenpantucel-L. WuXi will adapt facilities and equipment for production, generate batch records and other documents, perform studies and test manufacturing runs and conduct process validation and characterization, all of which we consider research and development until commercialization.

In addition to our HyperAcute platform, we have an active drug discovery and clinical development program focused on the IDO and TDO pathways. Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. In October 2014, we entered into an exclusive worldwide license agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of NLG919, one of the Company's IDO pathway inhibitors, and a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors or the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront

non-refundable payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating royalties on potential commercial sales of multiple products by Genentech.

Indoximod, another of the Company's IDO pathway inhibitors, is in multiple Phase 1 and 2 clinical trials for the treatment of patients with breast, prostate, pancreas and brain cancers.

Our small molecule IDO pathway inhibitor drug candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. In many different cancers, IDO can be overexpressed directly either on cancer cells or by antigen presenting cells in the tumor microenvironment, representing a substantial drug development opportunity. When IDO is expressed by developing cancers, IDO pathway activity creates an immunosuppressive environment that shifts the immune response from anti-cancer to cancer tolerance. Multiple elements of the immune system are affected by this shift, including T cells, regulatory T cells, and dendritic cells, resulting in the survival of malignant cells that might otherwise be recognized and attacked by the immune system. Inhibiting the IDO pathway reprograms the immune response from tolerance back to an active anti-cancer response.

Our infectious disease business, managed through our wholly-owned subsidiary, BioProtection Systems Corporation, or BPS, researches and develops 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 most likely to enter the human population through pandemics or acts of bioterrorism. We have two core technologies, each of which can be leveraged into the infectious disease or biodefense fields.

The first technology is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses. This platform, licensed from the government of Canada, utilizes the rVSV vector to induce immunity against Ebola and Marburg viruses when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharpe and Dohme Corp., or Merck, to develop and potentially commercialize our rVSV-EBOV (Ebola) vaccine product candidate. Under the Merck Agreement, we received an upfront payment of $30 million and a milestone payment of $20 million (which we earned in February 2015) and we have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. Clinical trials have begun in West Africa which have the potential to develop the data necessary to support the approval of our Ebola vaccine product candidate by the FDA.

The second technology is our HyperAcute immunotherapy technology, which we are using to focus on enhancing vaccines for infectious diseases. We have been investigating HyperAcute recombinant vaccine product candidates using H1N1, H5N1 and H7N9 influenza viruses in animal experiments. Other HyperAcute recombinant infectious disease vaccines are currently under investigation.

Our profits in 2014 have been primarily the result of large payments received in connection with the Genentech and Merck licensing transactions. We do not expect any similar transactions in 2015, we expect our losses to increase over the next several years as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval.

On October 25, 2011, we filed a Certificate of Amendment of our Restated Certificate of Incorporation with the Secretary of State of Delaware effecting a 2.1-for-one reverse split of our common stock. All share and per share amounts have been retroactively restated where applicable in the accompanying financial statements and notes for all periods presented.

Founded in 1999 and headquartered in Ames, Iowa, we have a clinical, research and development staff that is developing our pipeline of product candidates for potential commercialization. We have established offices in Austin, Texas, where we intend to build our own commercial organization through which we intend to market our oncology products in the United States, and in Devens, Massachusetts, where we manage the development of and strategic relationships relating to our Ebola vaccine product candidate. Finally, we have built a distribution facility in Ankeny, Iowa for the distribution of algenpantucel-L, if it is approved, and other potential products we may commercialize. Outside the United States we will either commercialize and distribute approved products or seek commercialization and distribution collaborators for our product candidates as we have done with Merck in the case of our Ebola vaccine product candidate.

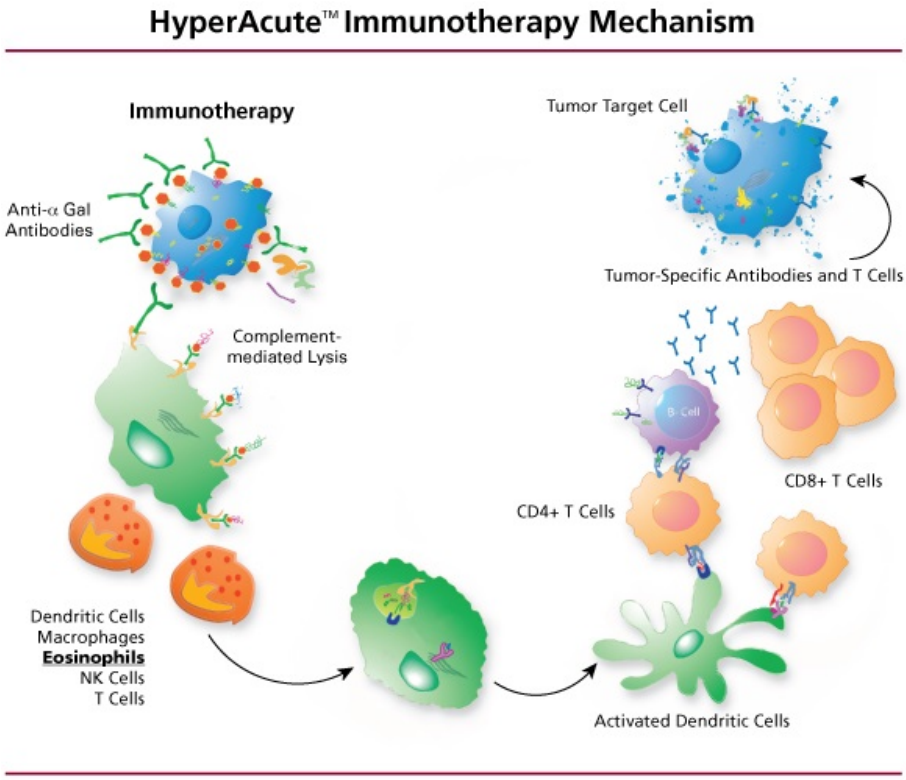
Our HyperAcute Cancer Immunotherapy Technology

Our HyperAcute immunotherapy platform consists of novel biologic products designed to stimulate the patient's immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human, tumor-specific cancer cell lines. These cells have been modified to express alpha-Gal, a carbohydrate to which humans have preexisting immunity. These alpha-Gal-modified cancer cells stimulate an immune response that "educates" the immune system to attack a patient's own cancer cells.

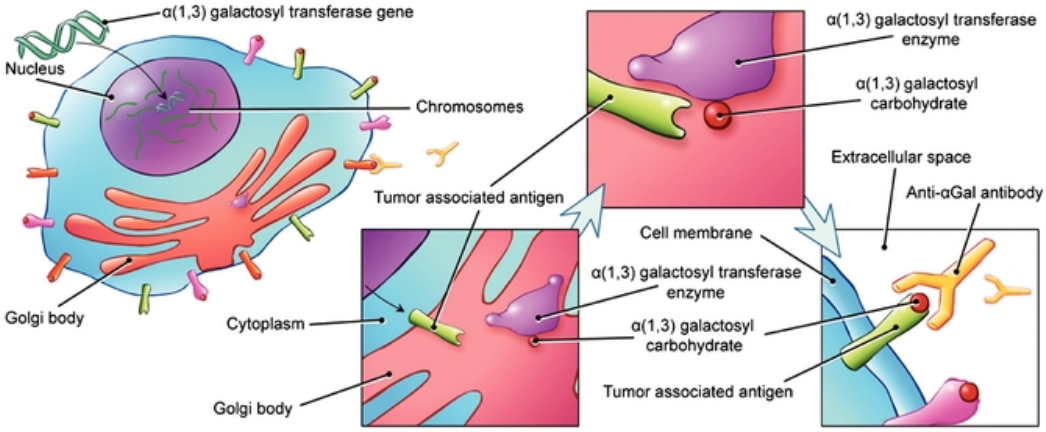
We believe that, compared to some prior immunotherapy approaches, our proprietary HyperAcute immunotherapy technology offers several advantages including:

- a robust inherent immune response that harnesses the human body's naturally protective and rapid immune reaction to the alpha-Gal carbohydrate as a mechanism to fight cancer;
- a complex targeted approach that is multi-faceted and involves combined antibody-mediated and multi-cellular responses; and
- an allogeneic, tumor-specific, but not 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. This barrier is related to the enzyme alpha-GT. The presence of this enzyme results in the expression of a carbohydrate called alpha-Gal on the surface of affected cells. Introducing alpha-Gal expressing cells to the immune system activates an immune response from preexisting antibodies against alpha-Gal.



Unlike some immunotherapies, HyperAcute immunotherapies do not require the harvesting of an individual's tissue or cancer cells in order to produce the vaccine. HyperAcute immunotherapies are manufactured using established tumor-specific human cell lines. In addition, HyperAcute immunotherapies use intact whole cells rather than cell fragments or purified proteins, which we believe results in the stimulation of an enhanced multi-faceted immune response against the patient's cancer.



HyperAcute immunotherapy product candidates are composed of irradiated, live, allogeneic human cancer cells modified to express the gene that makes alpha-Gal. Exposure to alpha-Gal stimulates the human immune system to attack and destroy the immunotherapy cells on which alpha-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-alpha-Gal antibodies are processed by the immune system to elicit an enhanced multi-faceted immune response to TAAs common to both the immunotherapy and the patient's tumor cells.

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 that 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 alpha-Gal carbohydrate.

HyperAcute immunotherapies are designed to break tolerance and enable longer duration of anti-tumor effect. We believe that our HyperAcute immunotherapy technology induces a combination of unique immune responses.

HyperAcute Pipeline

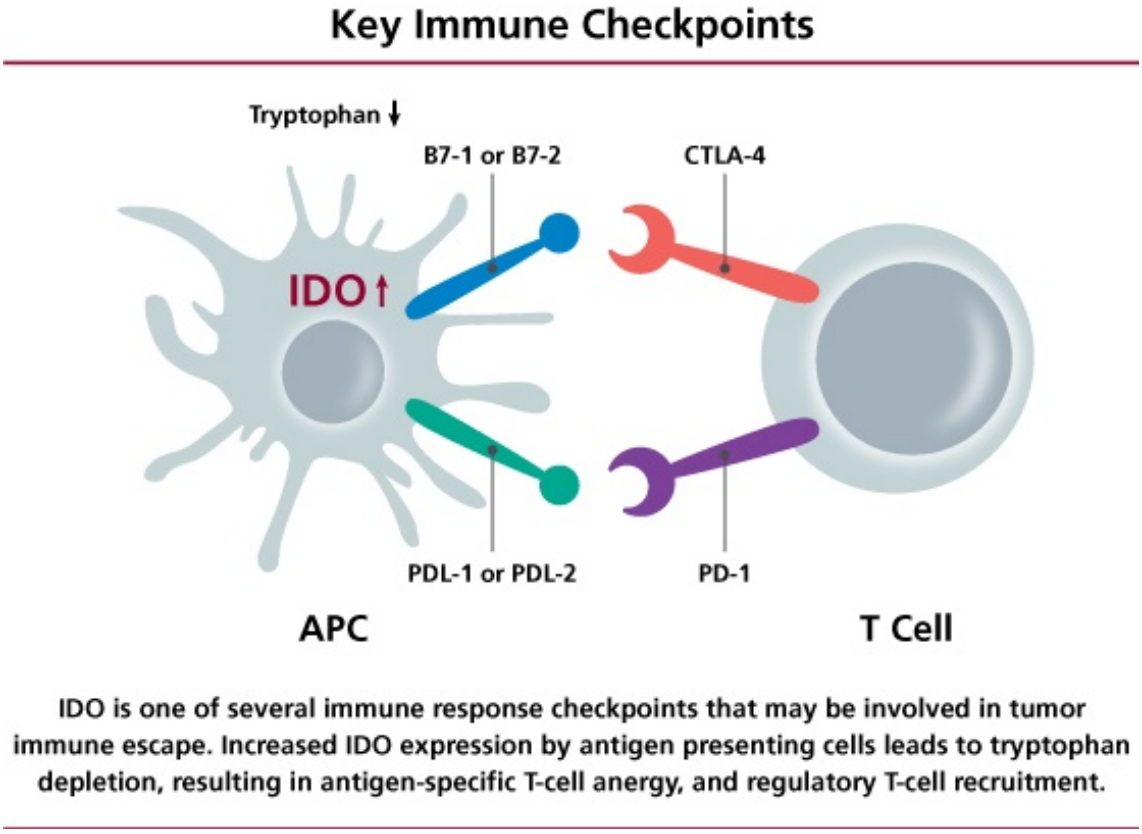
We have multiple HyperAcute immunotherapy product candidates currently under development specific to multiple types of cancer.

- Algenpantucel-L is currently being studied in two Phase 3 trials:
  - IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study)
  - PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable)
- Tergenpumatucel-L is being investigated in a Phase 2b/3 trial in advanced non-small cell lung cancer
- Dorgenmeltucel-L is being investigated in a Phase 2 trial in advanced melanoma

We have also created HyperAcute immunotherapies in other indications such as renal, prostate and breast cancers.

Our IDO Pathway Inhibitor Product Candidates

The IDO pathway inhibitor platform is focused on developing small molecule drugs that disrupt mechanisms by which tumors evade the patient's immune system. IDO pathway inhibitors are a class of immune checkpoint inhibitors akin to antibodies targeting CTLA-4 and PD-1, which represent a potential breakthrough in cancer therapy. Blocking IDO has been shown preclinically to reduce immunosuppression and enhance immune response offering the potential for enhanced anti-tumor response. IDO has demonstrated preclinical synergy in combination with other immunotherapies including other checkpoint inhibitors and cancer vaccines as well as chemotherapy or radiation.



The IDO pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. Recent studies indicate that the IDO pathway is active in many cancers, both within tumor cells as a direct defense against T cell attack, and also within antigen-presenting cells in tumor-draining lymph nodes resulting in peripheral tolerance to TAAs. Cancers may use the IDO pathway to facilitate survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system.

Our IDO pathway inhibitors are orally administered small molecules and can potentially be used alone or in combination with other cancer therapies including other checkpoint inhibitors such as those directed against CTLA-4 and PD-L1, cancer vaccines such as our HyperAcute vaccines and chemotherapy regimens for potential increased activity.

We are actively developing two IDO pathway inhibitors with broad potential across multiple tumor types. In October 2014, we entered into an exclusive worldwide license agreement with Genentech for the development and commercialization of NLG919, and a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating royalties on potential commercial sales of multiple products by Genentech. We did not license indoximod under the Genentech Agreement, and we expect to continue its development. Indoximod is in multiple Phase 1 and 2 clinical trials for the treatment of patients with breast, prostate, pancreas, and brain cancers.

Our IDO pathway inhibitors, indoximod and NLG919, are being investigated as part of various combination regimens including with other checkpoint inhibitors, and chemotherapy in metastatic breast cancer, metastatic prostate cancer, and other cancers.

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 algenpantucel-L, our lead HyperAcute pancreas immunotherapy product candidate, and gain regulatory approval.*
- *Develop manufacturing, distribution and market access infrastructure to commercialize algenpantucel-L in the United States and establish commercial collaborations in other regions.*
- *Expand the target market for algenpantucel-L for the treatment of patients with locally advanced pancreatic cancer.*
- *Advance our tergenpumatucel-L and dorgenmeltucel-L product candidates through additional clinical trials.*
- *Establish validated external manufacturing capacity for algenpantucel-L and potential subsequent HyperAcute products.*
- *Further develop our proprietary IDO pathway inhibitor Indoximod (D-1MT).*
- *Support the alliances with Genentech and Merck*
- *Strengthen our pipeline of immune stimulatory drug candidates, including our infectious disease business.*

Cancer Market Overview

Cancer is the second-leading cause of death in the United States; the American Cancer Society estimated that more than 500,000 deaths will occur in 2015. 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 66% for the period spanning 2004-2010 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 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.

- *Development of resistance.* 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.

Potential Advantages of HyperAcute Immunotherapy Over Current Cancer Therapies

We believe our HyperAcute immunotherapy has the following potential 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 alpha-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 alpha-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 standard chemotherapy or radiation regimens. Our HyperAcute immunotherapy technology is designed to stimulate a strong or robust immune response to specific cancer cells while limiting the risks of off-target effects.
- *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 Product Pipeline

The chart below summarizes our current product candidates and their stages of development. Our product candidate pipeline includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications.

PRODUCT	INDICATION	DESIGN DETAILS	PHASE 1	PHASE 2	PHASE 3
Algenpantucel-L	Pancreatic cancer (resected)	IMPRESS: Algenpantucel-L + standard of care; randomized	ENROLLMENT COMPLETE*		
	Pancreatic cancer (borderline resectable or locally advanced)	PILLAR: Algenpantucel-L + chemotherapy; randomized	ENROLLMENT MID 2015		
Tergenpumatucel-L	NSCLC (advanced or metastatic)	Tergenpumactucel-L vs. docetaxel and controlled for follow on chemotherapy; phase 2b/3; randomized	ENROLLMENT 2H 2015		

DISEASE/TUMOR TYPE	REGIMEN	STATUS
Metastatic Breast Phase 2	Indoximod + docetaxel or paclitaxel; randomized	Enrollment 2H 2015
Glioblastoma Phase 1b/2	Indoximod + temozolomide	Phase I enrollment complete
Metastatic Pancreatic 1b/2	Indoximod + gemcitabine and nab-paclitaxel	Enrollment 2H 2015

Our algenpantucel-L (HyperAcute Pancreas) Cancer Immunotherapy Product Candidate

Our lead HyperAcute product candidate, algenpantucel-L, is an investigational immunotherapy for pancreatic cancer. The product consists of two pancreatic cancer cell lines that have been genetically modified to express alpha-Gal carbohydrates on cell surface molecules. We believe that upon injection into the patient, the alpha-Gal stimulates an immune response against pancreatic cancer-specific antigens in the tumor cell lines. The patient's immune system then targets the patient's own pancreatic cancer cells, destroying them. In the adjuvant setting, the immune response targets and eradicates residual tumor cells in conjunction with chemotherapy or chemotherapy and chemoradiation.

Algenpantucel-L is currently being studied in combination with standard of care in two phase 3 trials:

- IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study)
- PILLAR (Pancreatic Immunotherapy with Algenpantucel-L for Locally Advanced Non-Resectable)

Our Phase 3 IMPRESS study in surgically-resected pancreatic cancer patients is being performed under an SPA with the FDA. Algenpantucel-L has also received Fast Track and Orphan Drug designations from the FDA for the adjuvant treatment of surgically-resected pancreatic cancer.

In May 2010, we initiated our Phase 3 IMPRESS clinical trial for algenpantucel-L. The SPA we have entered into with the FDA contemplated that we would enroll up to 722 patients, which, under the statistical plan contained in the SPA would enable us to demonstrate statistically significant improvement in median overall survival at the end of the trial. We completed enrollment in September 2013 with 722 patients and completed the first interim analysis of data in the first quarter of 2014. We project the second interim analysis of data from this study will occur in the first or second quarter of 2015.

We initiated the IMPRESS trial based on encouraging interim data from our Phase 2 clinical trial that was fully enrolled in March 2010. As of June 2012, all patients in this Phase 2 study had reached at least 24 months of follow-up with a median follow-up period of approximately 33 months. The study met its primary objective with an established median disease-free survival of 14.1 months. The secondary endpoint of overall survival showed one-year overall survival to be 86 percent. As of June 2012, 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 percent. Algenpantucel-L has demonstrated good tolerability and a favorable safety profile in the Phase 2 study. The most common treatment-related adverse reactions (reported by at least 5 percent of patients) for the product candidate included injection site reactions (40%), induration (19%), injection site pain (10%), pyrexia (9%), erythema (7%), fatigue (19%), nausea (6%), lymphopenia (6%) and pruritus (5%). All of these events were grade three or less. The common terminology criteria, or CTC, of the National Cancer Institute, or NCI, 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.

In 2013, we launched a Phase 3 study for algenpantucel-L in patients whose pancreatic cancer is locally advanced (PILLAR). This trial is expected to enroll 280 patients with borderline or locally advanced unresectable disease with the primary endpoint for the study being overall survival after treatment with a regimen of chemotherapy (either FOLFIRINOX or gemcitabine/nab-paclitaxel) with or without algenpantucel-L.

Market Opportunity

Pancreatic cancer is the fourth leading cause of cancer death in the United States and is one of the most difficult cancers to treat. Nearly 49,000 Americans are expected to be newly diagnosed with pancreatic cancer in 2015, and the incidence rates have been increasing since 2004. Approximately 25% of those patients will be eligible for surgical resection. Adjuvant therapy with chemotherapy or chemoradiation is standard of care postresection. However, the 5-year survival rate for these patients is less than 14%.

Current treatment recommendations for locally advanced pancreatic cancer usually include combined modality treatments with chemotherapy and radiotherapy. These treatments are rarely effective in shrinking a tumor to the point where it can be successfully resected. There is a trend toward using combination regimens that have shown benefits for conversion to resectability and increased survival. However, many of these regimens are associated with considerable toxicity. Treatment recommendations for advanced pancreatic cancer are primarily palliative in nature. There have been limited advances over the past 20 years with the most recent agents approved for use in the United States for patients with advanced pancreatic cancer offering modest survival benefits of approximately 2 months over previous approaches. There remains a critical need for novel therapies that can improve outcomes for patients with pancreatic cancer.

Clinical Trials

Phase 3 Clinical Trial (IMPRESS)

In May 2010, we initiated our IMPRESS Phase 3 clinical trial for algenpantucel-L. This trial is an open-label, randomized, controlled, multi-center Phase 3 clinical trial, evaluating 722 patients with Stage I and Stage II surgically-resected pancreatic cancer classified 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. In September 2013, we completed the enrollment of 722 patients in this clinical trial. Based on our discussions with the FDA, we believe this number of patients is adequate to demonstrate statistically significant improvement in median overall survival at the end of the 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 receive standard adjuvant therapy with algenpantucel-L and 50% receive standard adjuvant therapy without algenpantucel-L. 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, considering the observed dose response, we believe higher doses of treatment might provide further benefit. We therefore modified the treatment schedule for all patients receiving algenpantucel-L 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 overall survival when approximately one-half of the expected number of deaths have occurred and, 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. The first interim analysis occurred in the first quarter of 2014, and the trial's Data Safety and Monitoring Board determined to continue. We project the second interim analyses of data from this study will occur in the first or second quarter of 2015.

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 3 Clinical Trial (PILLAR)

The recent emergence of combination therapy with FOLFIRINOX (leucovorin, 5-FU, oxaliplatin and irinotecan) and gemcitabine / nab-paclitaxel has been promising in the metastatic disease and both regimens are being tested extensively in the locoregional disease setting. We believe that the addition of algenpantucel-L immunotherapy to FOLFIRINOX or gemcitabine / nab-paclitaxel combination chemotherapy has the potential to improve survival of patients in this population. To assess this potential treatment combination we initiated the PILLAR Phase 3 clinical study that will assess overall survival after treatment with a regimen of FOLFIRINOX or gemcitabine / nab-paclitaxel with or without algenpantucel-L immunotherapy in subjects who have borderline resectable or locally advanced unresectable pancreatic cancer. In addition to overall survival, secondary endpoints include assessment of progression free survival and correlative scientific studies of subject samples to determine the mechanism of any observed anti-tumor effect. In these studies human humoral and cellular immune responses to algenpantucel-L will be evaluated.

Phase 2 Clinical Trial

We have completed an open-label, two-armed Phase 2 clinical trial, referred to as NLG-0205, in which algenpantucel-L 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 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 also wanted to determine if a superior dosing regimen could 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. Patient enrollment was complete in March 2010.

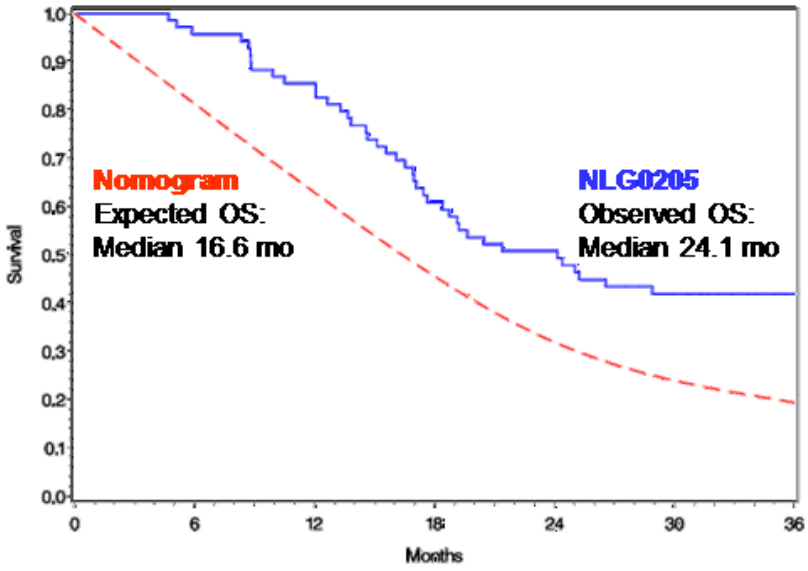
As of June 2012, all patients had reached at least 24 months of follow-up with a median follow-up period of approximately 33 months. To date, algenpantucel-L has demonstrated good tolerability and a favorable safety profile. The most common non-serious adverse events observed were fatigue, local injection 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 other HyperAcute immunotherapies. The study met its primary objective with an established median disease-free survival (DFS) of 14.1 months. The analyses of the secondary endpoint of overall survival for the entire study showed one-year overall survival of 86 percent and a Kaplan-Meier estimate predicts a median overall survival at 24.1 months. Subgroup analysis showed that patients receiving 300 million cells/dose had a 12-month DFS of 81 percent while those receiving 100 million cells/dose had a 12-month DFS of 51 percent (p=0.02, Fisher's exact), and a one-year overall survival rate of 96 percent and 79 percent 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 percent and a one-year overall survival rate of 69 percent based on Kaplan-Meier analysis.

Kaplan-Meier Analysis of Overall Survival in our Phase 2 Study

Kaplan-Meier analysis is a statistical method of predicting survival rates using study survival data. Nomogram analysis is a method for determining expected survival rates using patient baseline characteristics and other prognostic indicators. As shown in the graph below, the Kaplan-Meier-calculated overall survival in our Phase 2 clinical trial compares favorably to projected survival calculated by nomogram analysis.

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



The dotted line represents projected survival of patients enrolled in NLG-0205 based on the prognostic Brennan et al. Nomogram (*Brennan et al., Ann Surg, 2004, 240:293*), also known as the Memorial Sloan Kettering Cancer Center nomogram. The solid blue line represents the Kaplan-Meier estimated survival curve for patients enrolled in NLG-0205 as of June 2012. At 12 months after surgery overall survival for the combined patient population in NLG-0205 is 86%. The observed median overall

survival is 24.1 months for the combined patient population in NLG-0205 versus 16.6 months predicted by the Brennan et.al. Nomogram.

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 algenpantucel-L 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 data from NLG-0205 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 compared to low dose patients was observed (96% vs. 79%, 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 analysis 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.

Survival Outcome of NLG0205 vs predicted and RTOG 97-04

	Disease-Free Survival at 1 year	Overall Survival at 1 year
Predicted Brennan et al., 2005 nomogram	Not Applicable	63%
RTOG 97-04 (221 patients)	<50%*	69%
NLG-0205-100 million cell dose group	51%	79%
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%.

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 algenpantucel-L 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.

Study	Nodal Status (%N+)	Local Invasion	Tumor Stage (T3/T4)	High Tumor Grade	Ca 19-9 (≥ 180 U/mL)	Disease-Free Survival Median (Months)	Overall Survival Median (Months)	Overall Survival at 1 Year
RTOG 97-04 2008(1)	**68 %**	**Not reported**	**81 %**	**32%***	**14%(2)**	**11/4/2003**	**20.5(3)**	**69 %**
Treatment Arm:								
Gemcitabine + 5FU +								
Radiation (221 patients)								
NLG-0205 (4)	**81 %**	**90%***	**83 %**	**36%***	**17%***	**14.1**	**24.1**	**86 %**
Gemcitabine + 5-FU +								
Radiation + Algenpantucel-L								
(69 patients)								

(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) Hardacre JM, mulcahy KA, Small EJ, et al: Addition of Algenpantucel-L Immunotherapy to Standard Adjuvant Therapy for Pancreatic Cancer: a Phase 2 Study J Gastrointest Surg DOI 10.1007/s11605-012-2064-6, 2012.
* 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.

Because comparisons between specific studies can have limited validity, researchers have developed statistical tools to evaluate the likely impact of therapies on overall survival. One such tool is the Brennan et. al. Nomogram developed at Memorial Sloan Kettering Cancer Center for surgically resected Stage I/II patients based on the interaction of baseline patient characteristics and other prognostic indicators.

Among the U.S.-based comparator studies, 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 algenpantucel-L to a chemoradiotherapy protocol highly similar to that used in RTOG 97-04. As calculated by applying Brennan et. al. Nomogram analysis to the patient characteristics and other prognostic indicators of the respective studies, the projected overall survival of patients in the RTOG 97-04 study is higher than the projected overall survival of patients in the NLG-0205 study.

Our tergenpumatucel-L (HyperAcute Lung) Cancer Immunotherapy Product Candidate

Tergenpumatucel-L is an investigational HyperAcute immunotherapy for non-small cell lung cancer, or NSCLC. The product consists of three NSCLC cell lines that have been genetically modified to express alpha-Gal carbohydrates on cell surface molecules. Upon injection into the patient, the alpha-Gal stimulates a rapid and powerful immune response against NSCLC-specific antigens in the tumor cell lines. We believe the patient's immune system then targets the patient's own NSCLC cancer cells, destroying them. In a phase 2b/3 study in progressive or relapsed NSCLC, two different dosing schedules of tergenpumatucel-L are currently being compared to docetaxel with a primary endpoint of overall survival. This study is also evaluating the potential for chemosensitization to salvage regimens post tergenpumatucel-L exposure.

Market Opportunity

According to the American Cancer Society, NSCLC is the leading cause of cancer death among both men and women in the United States, with more than 150,000 Americans expected to die from this devastating disease in 2015. Of more than 200,000 newly diagnosed patients expected in 2015, approximately 40% will present with metastatic disease, for which there are significant limitations in treatment options. Best supportive care is the only option for many of these patients with NSCLC, and survival outcomes remain poor. The 5-year survival rates for advanced NSCLC are only 5% for Stage IIIB disease and 1% for Stage IV disease, which underscores an urgent need for innovative therapies.

Phase 1/2 Clinical Trial

Tergenpumatucel-L was studied in a Phase 1/2, single-arm, open-label clinical trial that fully enrolled with 54 patients at the NCI. This clinical trial was for patients with refractory, recurrent or metastatic NSCLC. Its primary endpoint was to assess tumor response rate after administration of tergenpumatucel-L, and the secondary endpoint was 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 tergenpumatucel-L. 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 Phase 1 portion of our Phase 1/2 clinical trial for our tergenpumatucel-L immunotherapy 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 tergenpumatucel-L. The most common treatment-related adverse reactions (reported by at least 5% of patients) for tergenpumatucel-L, were injection site reaction (88%), induration (51%), fatigue (25%), urticaria (10%), anemia (5%), 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 candidates conducted to date.

Results of our Phase 1/2 clinical trial for tergenpumatucel-L, based on the analysis of 45 patients, were encouraging. As of January 2012, the results for the 28 patients evaluated in the Phase 2 clinical trial group showed a median progression-free survival of 3.4 months, 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.

Immunological studies showed that tergenpumatucel-L induced the increase of IFN-gamma secreted post immunization by peripheral blood lymphocytes in 11 of 18 tested patients. Patients that responded with increased IFN-gamma secretion post immunization had significantly increased overall survival when compared to non-responding patients (21.9 vs 7.2 months p=0.044).

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. The following table shows comparative results for second-line treatment in advanced NSCLC with pemetrexed, docetaxel and tergenpumatucel-L.

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 %	—%	—%	—%	—%

(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

Given the favorable safety profile of tergenpumatucel-L, and the 11.3 month median overall survival observed in the Phase 2 study, tergenpumatucel-L compares favorably to current standard-of-care cytotoxic chemotherapy.

In 2013, enrollment started on our phase 2B/3 clinical trial in non-small cell lung cancer. When available, the results of the Phase 2B portion of the study will assist in the design of the Phase 3 portion of the study.

Our dorgenmeltucel-L (HyperAcute Melanoma) Cancer Immunotherapy Product Candidate

Our dorgenmeltucel-L (HyperAcute Melanoma) product candidate was studied in an investigator-initiated Phase 2 clinical trial in 25 patients with advanced melanoma. In this trial, dorgenmeltucel-L was 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. Dorgenmeltucel-L consists of a group of three allogeneic melanoma tumor cell lines that were modified to express the gene that makes alpha-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 dorgenmeltucel-L cell line are given by intradermal injection with each treatment.

Market Opportunity

According to the American Cancer Society, the incidence of melanoma in the United States has been increasing for the last 30 years. Most cases of melanoma (84%) are diagnosed at an early stage, when curative treatment with surgical excision is possible. However, melanoma can recur after surgery, and about 13% of patients present with regionally advanced or metastatic disease. For patients with stage IIIC disease, 5-year survival has been reported to be 40%. Only 15-20% of patients with metastatic disease will survive for 5 years or more.

Phase 2 Clinical Trial

We provided dorgenmeltucel-L product 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 completed enrolling 25 patients in September 2010. The treatment consisted of 12 weekly injections of dorgenmeltucel-L with PEG-Intron co-administered in weeks five through 12. This was the first time that one of our HyperAcute immunotherapies was combined with another approved immunotherapy, in this case PEG-Intron. The primary objective of this clinical trial was 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.

As of June 2012, vitiligo had been 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 dorgenmeltucel-L. Dorgenmeltucel-L 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 treatment-related adverse events reported included injection site reactions (92%), induration (76%), pruritis (16%), fatigue (52%), fever (32%), diarrhea (52%), nausea (44%), vomiting (8%), rigors or chills (8%), head pain (52%), muscle pain (52%) and anorexia (28%). By Response Evaluation Criteria in Solid Tumors, or RECIST criteria, of 16 stage IV patients, there were two complete responders (CR), two with stable disease (SD) and two with no evidence of disease (NED) after resection. For the one stage II and eight stage III patients, three of nine (3/9) remain NED, with one patient with slowly progressive disease remaining alive at 30 months. The median overall survival is 29 months, with 50% of the patients surviving for two years. In conclusion, combination immunotherapy with dorgenmeltucel-L plus PEG-Intron shows signs of clinical efficacy with tumor regression and concomitant immune activation.

We have begun enrolling a Phase 2 trial of dorgenmeltucel-L in combination with ipilimumab for advanced melanoma. The design is a randomized Phase 2 design that comopares standard of card ipilimumab to ipilimumab plus dorgenmeltucel-L. We used the statistically significant improvements in outcomes resulting from higher doses in our Phase 2 clinical trials with algenpantucel-L (HyperAcute Pancreas) to inform our Phase 2 combination trial. Specifically, in the Phase2 clinical trial of our dorgenmeltucel-L 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 algenpantucel-L, data from our Phase 2 clinical trial of algenpantucel-L (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. Therefore, we used a higher dose of dorgenmeltucel-L for a longer period of time (24 total doses over 24 months) in our current Phase 2 dorgenmeltucel-L 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 initiated development for our HyperAcute Prostate, HyperAcute Breast and HyperAcute Renal product candidates and are developing our HyperAcute immunotherapy technology for other indications.

Our IDO Pathway Inhibitor Technology

The IDO pathway inhibitor platform is focused on developing small molecule drugs that disrupt mechanisms by which tumors evade the patient's immune system. IDO pathway inhibitors are a class of immune checkpoint inhibitors akin to the antibodies targeting CTLA-4 and PD-1, which represent potential breakthroughs in cancer therapy. Our IDO pathway inhibitors are orally administered small molecules and can potentially be used alone or in combination with other cancer therapies.

The IDO pathway regulates immune response by suppressing T cell function and enabling local tumor immune escape. Recent studies indicate that the IDO pathway is active in many cancers, both within tumor cells as a direct defense against T cell attack, and also within antigen-presenting cells in tumor-draining lymph nodes resulting in peripheral tolerance to TAAs. Cancers may use the IDO pathway to facilitate survival, growth, invasion, and metastasis of malignant cells expressing TAAs that might otherwise be recognized and attacked by the immune system.

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 tumor 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 indoximod, 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 IDO pathway inhibitors are 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 immunotherapy or chemotherapy has the potential to enhance the therapeutic effect of these agents. Used in combination with chemotherapy IDO inhibitors have the potential to delay or disrupt the reacquisition of immune tolerance to tumor antigens during the period following chemotherapy. In addition, preclinical studies have demonstrated the synergistic potential of IDO pathway inhibitors in combination with other cancer immunotherapies, including other checkpoint pathway inhibitors as well as cancer vaccines. 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.

Our IDO Pathway Inhibitor Product Candidates

We have an active drug discovery and clinical development program focused on the IDO and TDO pathways. Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. In October 2014, we entered into an exclusive worldwide license agreement with Genentech, for the development and commercialization of NLG919, and a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating royalties on potential commercial sales of multiple products by Genentech. We did not license indoximod under the Genentech Agreement, and we expect to continue its development. Indoximod is in multiple clinical trials for the treatment of patients with breast, prostate, pancreas and brain cancers.

Clinical Trials of Indoximod

Phase 1B/2 Clinical Trials

Indoximod has successfully completed initial phase 1 development. Phase 1 studies evaluating indoximod were done in cooperation with the National Cancer Institute's Division of Cancer Treatment and Diagnosis and enrolled a total of 65 patients. Indoximod was well tolerated and a Ready for Phase 2 Dose (RP2D) was determined. No dose limiting toxicities were observed. Under the same partnership, a Phase 1b trial of indoximod in combination with docetaxel for patients with advanced solid tumors

was performed. The combination was well tolerated, a Phase 2 dose for the combination was determined, and clinical responses were observed.

Currently, indoximod is in being developed by us in a variety of combinations across several cancer indications:

- NLG2101 phase 2 trial of indoximod in combination with taxane chemotherapy for patients with metastatic breast cancer continues to enroll patients with full enrollment expected in 2015.
- NLG2102 phase 1b/2 trial of indoximod in combination with temozolomide for patients with refractory malignant brain tumors.
    - Phase 1 portion is fully enrolled with results expected to be reported in mid 2015.
- NLG2103 phase 1b/2 trial of indoximod in combination with ipilimumab for patients with advanced melanoma.

- NLG2014 phase 1b/2 trial of indoximod in combination with gemcitabine / nab-paclitaxel for patients with metastatic pancreatic cancer.

Infectious Disease

Historically, in addition to our oncology programs, we have carried out an infectious disease program through our subsidiary, BioProtection Systems Corporation, or BPS. BPS was founded by us 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 enter the human population through either pandemics or even acts of bioterrorism. In 2010, we owned a majority of BPS' common stock on an as-converted basis. On January 7, 2011, we acquired the remaining minority interest in BPS and BPS became a wholly-owned subsidiary of us.

Our infectious disease program is based upon two core technologies, each of which can be leveraged into the infectious disease or biodefense fields. The first technology is replication competent recombinant Vesicular Stomatitus Virus, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses and licensed from the Public Health Agency of Canada, or PHAC. In November 2014, we entered into the Merck Agreement to develop and potentially commercialize our Ebola vaccine product candidate. We received an upfront payment of $30 million, and a milestone payment of $20 million (which we earned in February 2015) and we have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and Merck successfully commercializes it. Clinical trials have begun in West Africa which have the potential to develop the data necessary to support the approval of our Ebola vaccine product candidate by the FDA.

The second technology is our HyperAcute immunotherapy technology, which is currently focused on enhancing vaccines for influenza.

Grants and Contracts with the United States Government

Other than the upfront payments from Genentech and Merck, grants and contracts between BPS and the United States Government accounted for substantially all of our revenue in each of the last three fiscal years. In December 2014, we announced that the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services had awarded us a contract, as the prime contractor, in the amount of $30 million to support the manufacturing and development activities of our Ebola vaccine product candidate, including clinical development through a new 330-person Phase 1b study. We have also received funding from the United States Department of Defense to support the development of contract manufacturing for the vaccine product candidate for both clinical trials and, ultimately, for large-scale vaccination in the event the vaccination candidate is approved for such use.

Manufacturing

We manufacture our HyperAcute immunotherapies at our facilities in Ames, Iowa. We believe this facility is adequate to supply all of the Phase 3 clinical trial drug requirements for at least two HyperAcute product candidates. In addition, we have entered into an agreement with WuXi to produce algenpantucel-L in bulk for the commercial market, when or if it is approved. WuXi is building capacity and working with us to validate its processes and equipment in the event that clinical data will support an application to FDA for approval of algenpantucel-L. We have established our own facility in Ankeny, Iowa to manage the final production steps, including irradiation and packaging, and to distribute our potential vaccine drug products, if any are approved.

We currently contract with Regis Technologies, and with University of Iowa Pharmaceutical Services for the manufacture of our indoximod drug product. 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.

Genentech will be responsible for the manufacturing of NLG919 and any other drug candidate developed in accordance with the Genentech Agreement.

We have entered into an agreement with an established contract manufacturing organization to produce our Ebola vaccine product candidate. After a transition period and subject to conditions, Merck will assume responsibility for manufacturing the Ebola vaccine product candidate in accordance with the Merck Agreement.

Sales and Marketing

We currently own exclusive worldwide commercial rights to our HyperAcute immunotherapy and indoximod product candidates. If we obtain approval for any of these product candidates, excluding NLG919, we intend to build a commercial infrastructure targeting oncologists and cancer centers in the United States. In 2014, we established an office in Austin, Texas to serve as the headquarters of our commercial organization. In addition, we may pursue collaborations 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 a fully integrated and highly experienced team, consisting of sales, marketing, medical affairs, market access and other positions necessary for a successful product launch in the U.S. market. Our lead product candidate, algenpantucel-L is anticipated to be approved for patients with resected pancreatic cancer. We anticipate that a moderately sized, focused and highly experienced sales team will be sufficient to reach key institutions and cancer centers treating pancreatic cancer patients. Additional support for our commercialization efforts may be provided by both medical affairs and market access professionals, who will provide the needed education, reimbursement support and other key functions needed to support an oncology product launch in the United States. We anticipate the need to hire personnel in advance of the approval of any of our product candidates and in 2014, hired officers and other personnel in medical and clinical affairs, market access, and marketing to prepare for a possible launch of algenpantucel-L.

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. 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 are developing or have commercialized cancer immunotherapy products, including Genentech, 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.

Algenpantucel-L (HyperAcute Pancreas)

There are no anti-cancer drugs currently approved by the FDA for patients with resected pancreatic cancer, but several large public biopharmaceutical companies are developing or have commercialized cancer immunotherapy products, including Genentech, 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. Additionally, there are numerous generic drugs approved for advanced pancreatic cancer including gemcitabine, fluorouracil and mytomycin C. A number of companies have 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.

Tergenpumatucel-L (HyperAcute Lung)

There are numerous companies actively marketing FDA approved drugs for patients with NSCLC. These include Celgene wtih Abraxane (nab-paclitaxel), Genentech/Roche with Avastin (bevacizumab), Eli Lilly with Alimta (premetrexed), Astellas/Genentech with Tarceva (erlotinib) and Pfizer with Zalkori (crizotinib). Additionally, there are a number of generic drugs approved by the FDA for use in NSCLC, including cisplatin, docetaxel, paclitaxel, gemcitabine, vinorelbine and methotrexate. There are a large 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.

Dorgenmeltucel-L (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 drug manufacturers. 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.

Strategic Collaborations

Genentech Agreement

In October 2014, we entered into the Genentech Agreement for the development and commercialization of NLG919, our clinical stage IDO pathway inhibitor, and a research collaboration for the discovery of next generation IDO/TDO inhibitors to be developed and commercialized under the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150 million. We may be eligible to receive in excess of $1 billion in milestone payments based on achievement of certain predetermined development, regulatory and sales milestones, as well as escalating royalties on potential commercial sales of multiple products by Genentech. The rates of such royalties will vary based on the stage of the compound at the signing of the Collaboration Agreement, regulatory exclusivity, intellectual property status, and other considerations.

Genentech will be responsible for and will fund future research, development, manufacturing and commercialization of NLG919 and next generation IDO/TDO compounds. Genentech will also provide us with funding to support our participation in the research collaboration. We have the right to continue to pursue development activities associated with the combination of NLG919 with our novel HyperAcute vaccine platform. Additionally, we have retained the option under the Genentech Agreement to co-promote NLG919 and next generation IDO/TDO products with Genentech in the United States, subject to certain conditions, if and when such products are approved for sale.

Under the Genentech Agreement, we granted to Genentech an exclusive, sublicensable, royalty-bearing license under certain of our patents and know-how relating to IDO/TDO, and we have agreed to work exclusively with Genentech with respect to IDO/TDO compounds for a specified number of years.

Unless earlier terminated, the Genentech Agreement will continue in effect for as long as Genentech has payment obligations to us. Each party may terminate the Genentech Agreement for the other party's uncured material breach of the Genentech Agreement or the other party's bankruptcy or insolvency. After the end of the research collaboration, Genentech may terminate the Genentech Agreement for convenience upon 180 days written notice.

We have retained all rights to Indoximod, including the ability to develop, commercialize, license and divest Indoximod in our discretion.

Merck Agreement

In November 2014, we entered into the Merck Agreement to research, develop and potentially commercialize our Ebola vaccine product candidate. The Ebola vaccine product candidate was originally developed by PHAC. Under the Merck Agreement, we received an upfront payment of $30 million and a milestone payment of $20 million (which we earned in February 2015), and we have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. Clinical trials have begun in West Africa which have the potential to develop the data necessary to support the approval of our Ebola vaccine product candidate by the FDA.

Under the terms of the Merck Agreement, Merck will be granted the exclusive rights to the Ebola vaccine product candidate, as well as any follow-on products. The Ebola vaccine product candidate is under an exclusive licensing arrangement with BioProtection Systems, our wholly-owned subsidiary and a licensee of PHAC. Under these license arrangements, PHAC retains non-commercial rights pertaining to the vaccine candidate.

Unless earlier terminated, the Merck Agreement will continue in effect for as long as Merck has royalty payment obligations to us. Merck may terminate the Merck Agreement for convenience upon a specified period of notice or for certain safety reasons with immediate effect. In the event of Merck's uncured material breach of its obligations under the Merck Agreement with respect to a particular product, we may terminate the Merck Agreement with respect to that product. We may also terminate the Merck Agreement with respect to certain products in the event Merck pursues an alternate product under certain circumstances. Each party may terminate the Merck Agreement for the other party's bankruptcy or insolvency

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 U.S. 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 December 31, 2014, our patent portfolio included ten patent families relating to our HyperAcute technology and twenty-two 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 three pending patent applications and 23 registered U.S. and foreign patents related to the HyperAcute technology. This patent family is expected to provide basic composition of matter patent protection and methods of manufacturing and use of such compositions extending until 2024 and has already resulted in granted patents in U.S. (US 7,763,641, US 8,551,474 and US 8,535,658), Europe (EP 1549353 B1), Mexico (278681), Japan (4966496) and Canada (2501744), all covering pharmaceutical compositions for inhibiting pre-established tumor growth comprising attenuated allogeneic tumor cells modified with alpha-Gal. Similar composition claims as well as methods of use for treating pre-established tumors are currently being further pursued in the U.S. and China.

The second principal family of patents is exclusively licensed from Drexel University and includes U.S. Patent No. 5,879,675 relating to the use of alpha-Gal in viral and cancer vaccines which expires in 2016. We exclusively license from Central Iowa Health System or own several other patents relating to alpha-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 alpha-Gal expiring in 2016 (US 7,005,126); and three applications issued in the United States (US Patents No. 7,998,486, 8,357,777 and 8,916,169) and three pending applications in both the United States and Europe covering isolated tumor antigens comprising alpha-Gal residues. The issued United States patents expire in 2020, 2027 and 2028, respectively, while the pending applications are projected to expire in 2027. Additional patent applications have been filed covering the use of carbohydrate-modified glycoproteins (PCT/US2014/025702, PCT/US2013/026271) and US

13/463,420, chemosensitization by Hyper Actute vaccines (PCT/US2014/040854). and correlates of efficacy to tumor vaccine (PCT/US2014/038231).

Our IDO pathway inhibitor technology patent portfolio contains several key U.S. patent families exclusively licensed from Georgia Regents Research Institute, formerly known as the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The first patent family contains five issued U.S. patents expiring in 2018, 2019 and 2021. This family contains patents having claims to pharmaceutical compositions of 1-methyl-tryptophan (US 8,198,265), 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 three issued U.S. patents directed to pharmaceutical compositions of indoximod (US 8,232,313, expires in 2024) and to methods of using indoximod to treat cancer (US 7,598,287 and US 8,580,844 expires in 2027and 2025, respectively). Related applications directed to the use of indoximod to activate T cells are granted in Australia and Canada (AU 2008200315 B2 and CA 2483451 C).

We believe additional barriers to entry in the IDO space are provided through exclusive licenses with Lankenau Institute for Medical Research (LIMR) 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 families of inhibitor compounds and second generation products. Four patent families that cover different classes of IDO inhibitor compounds and methods of treatment of cancer have been licensed from LIMR and are represented by several international pending cases and the issued patents US 7,714,139, US 8,476,454, CA 2520586, US 7,705,022, US 8,008,281, JP 4921965, CN ZL200480014321.1, CA 2520172, US 8,383,613, US 8,389,568. An additional patent family co-owned by us and LIMR covers compositions and methods of use of another family of IDO inhibitor compounds (PCT/US2009/041609, with issued patents US 8,748,469, China 102083429 and pending applications in Europe and Japan). Additionally, three patent families covering compositions of matter and methods of use of different classes of IDO inhibitor compounds are fully owned by us 1) PCT/US2008/085167 with granted applications in Europe (EP2227233), China, Japan and Hong Kong; 2) PCT/US2010/054289, with granted patents in the US (8,722,720), and 3) PCT/US2012/033245, which covers the IDO inhibitor compound NLG919, currently in clinical development, and its national counterparts are set to provide protection at least until 2032. This patent has already been granted in Europe (EP12715295.7) and Australia (2012242871), with multiple national applications still pending which are set to provide protection until at least 2032.

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, any of 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, as amended on December 30, 2013 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 or 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 or our sublicensees 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, in addition to the royalties described above, a percentage of certain consideration paid by the sublicensee to us. We have no obligation to pay fees to CIHS as a result of payments between us and our affiliates.

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 and we fail to cure such failure, CIHS may terminate, or convert the license to a non-exclusive license with respect to such particular field.

Unless terminated earlier, the CIHS Agreement will 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, after 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.

On December 30, 2013, we entered into an amendment to the CIHS Agreement, or the CIHS Amendment. Under the terms of the CIHS Amendment, certain provisions of the CIHS Agreement were amended, in part to clarify that we are not obligated to pay fees to CIHS as a result of payments between us and our affiliates with respect to the intellectual property rights licensed by CIHS to us pursuant to the CIHS Agreement. The CIHS Amendment includes, without limitation, clarifications to (i) the definitions of “Third Party(ies)” and “Net Sales”, (ii) provisions with respect to our obligations to take actions to enable CIHS to meet its obligations under certain federal statutes and (iii) provisions with respect to the sublicensing fee payable by us to CIHS. In addition, the CIHS Amendment updates the list of patents that are licensed to us under the CIHS Agreement. We entered into the CIHS Amendment in connection with our sublicensing of certain intellectual property to our wholly-owned foreign subsidiary.

Drexel University License Agreement

We are a 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 alpha-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 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, 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, and LIMR agrees to notify and provide us with a first look at any additional research findings that directly result from such use of the technology. 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 one time milestone payments in an aggregate amount up to approximately $1.36 million, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, subject to reduction for our royalty payments to third parties. 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. We have the responsibility, at our expense, to conduct the prosecution and maintenance of the LIMR patent rights licensed to us under the agreement.

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, and we may terminate the agreement upon a specified period of notice. 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.

Georgia Regents Research Institute License Agreement

We are a party to a License Agreement dated September 13, 2005, or the GRRI Agreement, with Georgia Regents Research Institute, or GRRI, which was formerly known as the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The GRRI Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013 and July 10, 2014. The GRRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified GRRI 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 GRRI's retained right to use, and to permit its academic research collaborators to use, such GRRI 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 GRRI, not to be unreasonably withheld or delayed.

In consideration of such license grant, we are obligated to pay to GRRI 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 GRRI, we must pay to GRRI 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, GRRI 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, GRRI may convert our license in such field to a non-exclusive license.

Unless terminated earlier, the GRRI Agreement will remain in effect until the expiration of the last licensed GRRI 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. GRRI 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 GRRI 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 GRRI.

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:

The Ohio State University License Agreement

We are a party to a license agreement dated June 28, 2013 with The Ohio State University, or OSU. This agreement grants us exclusive rights in the United States and its territories, in all fields of use, to patents related to pharmaceutical compositions and vaccines comprising antigens associated with L-Rhamnose and Forssman epitopes, including patent application US 13/463,420, which is co-owned by us and OSU.

In consideration of the license grant, we are obligated to pay OSU specified license fees and are obligated to pay to OSU specified annual license maintenance fees, patent prosecution and maintenance costs, potential milestone payments in an aggregate amount up to approximately $2.75 million for the first licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, with minimum royalties for the first three years in which a licensed product generates revenue. In addition, if we grant a sublicense under this agreement, we must also pay to OSU a percentage of certain consideration received by us from the sublicensee. Under this agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products and to use commercially reasonable efforts to achieve certain milestones by agreed-upon deadlines.

Unless terminated earlier, the agreement will continue until the expiration of the last licensed patent rights. We may terminate the agreement at any time for any reason with 90 days prior written notice. OSU may immediately terminate the agreement if we materially breach our obligations to OSU and do not cure the breach within the specified period, or if we or our affiliates or sublicensees participates in a challenge to the validity, enforceability or scope of the licensed patents. The agreement will also terminate if we agree with OSU that the agreement should be terminated or if we cease business operations or become involved in any bankruptcy, insolvency or liquidation-related activities. If the agreement is terminated, we will lose our license from OSU to the licensed patents but we will retain our rights as owners of all licensed patents that are co-owned by us and OSU.

Public Health Agency of Canada License Agreement

BPS is a party to a license agreement dated May 4, 2010, with PHAC, or the PHAC License. The PHAC 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 PHAC patent rights and technology to improve the patent rights, carry out educational purposes, and development of the patent rights where BPS cannot obtain regulatory approval or meet demand. BPS may grant sublicenses under the PHAC License, provided that each sublicense is consistent with the terms and conditions of the PHAC License and contain certain mandatory sublicensing provisions.

In consideration of the license grant, BPS must pay to Canada 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, PHAC may terminate the PHAC License.

In November 2014, we entered into a licenses and collaboration agreement with Merck to develop and potentially commercialize our Ebola vaccine product candidate. The Merck Agreement includes a sublicense of the patents subject to the PHAC License.

Unless terminated earlier, the PHAC License will remain in effect until the expiration of the last of the PHAC 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 PHAC 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 PHAC 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 of their acceptance for filing. 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

A Fast Track product is 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 FDA's 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 algenpantucel-L.

Orphan Drug Designation

We were granted Orphan Drug designation for algenpantucel-L 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.

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. 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.

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.

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 applicant and patent holders once the ANDA has been accepted for filing by the FDA. The NDA applicant 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 FDA policies, a drug or biologic candidate is eligible for priority review, or review within a six-month time frame from the acceptance for filing of an NDA or BLA, 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 ordinarily meets 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 Healthcare Laws

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

Federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, are also applicable to our business. We could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. The laws that may affect our ability to operate include: the federal Anti-Kickback Statute, which prohibits soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or

other third-party payers that are false or fraudulent; and the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters and was amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. There are also state law equivalents of each of the above federal laws, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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.

On November 4-5, 2012, the Committee for Orphan Medical Products, or COMP, recommended to the European Commission that HyperAcute Pancreas (algenpantucel-L) be designated as an orphan medicinal product, and the recommendation was formally accepted by the European Commission.

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. 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 that are expected to have a material impact on our operations.

Employees

As of December 31, 2014 we had 130 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 approximately 26,600 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, 2020, and we have the option to extend the lease for two 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 under the terms of a lease that expires October 31, 2015.

On November 14, 2011, we entered into a Memorandum of Agreement, or the Memorandum, with Iowa State University Research Park Corporation, or ISURP. The Memorandum is an addendum to the lease, or the Lease, dated September 30, 2009 between us and ISURP covering our facilities in Ames, Iowa. The Memorandum added approximately 26,600 square feet of additional space to the Lease. During 2012 operating rents to ISURP increased by $211,000. During 2012, ISURP provided a building allowance of $622,000 and assisted in securing an additional $456,000 in debt financing for us.

On December 29, 2014, we added an additional 6,770 square feet of offices located in the Iowa State University Research Park in Ames, Iowa. The lease expires January 31, 2018.

On February 24, 2014, we signed a lease for a 6,430 square foot commercial facility in Austin, Texas and amended the lease in February 2015. We anticipate conducting activities at this location associated with expansion of our commercialization efforts as well as supporting the continued growth of our clinical operations activities. Subsequent to the end of the year, we added an additional 3,468 square feet to Austin, Texas. The lease expires September 30, 2016.

On August 25, 2014, we entered into a lease for 47,250 square feet of space in Ankeny, Iowa. We anticipate conducting activities at this location associated with packaging and distribution. The lease expires October 31, 2017.

On December 15, 2014, we entered into a lease for 1,310 square feet of office space in Devens, Massachusetts to support our development efforts related to our Ebola vaccine product candidate. The lease expires December 14, 2015.

Corporate Information

We were incorporated in the state of Delaware on June 4, 1999 under the name “NewLink Genetics Corporation.”

Available Information

Our website address is www.linkp.com; however, information found on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K. We make available free of charge on or through our website copies of our Annual Report, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. 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 substantial risks and uncertainties. Our actual results could differ materially 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 algenpantucel-L for patients with resected pancreatic cancer. If we fail to complete, or fail to demonstrate safety and efficacy in clinical trials, fail to obtain regulatory approval or fail to successfully commercialize algenpantucel-L, 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 algenpantucel-L. The FDA must approve algenpantucel-L before it can be marketed or sold. Our ability to obtain FDA approval of algenpantucel-L depends on, among other things, completion of one or both of our Phase 3 clinical trials, whether our Phase 3 clinical trials of algenpantucel-L demonstrate statistically significant achievement of the applicable clinical trial endpoints with no significant safety issues and whether the FDA agrees that the data from either of our Phase 3 clinical trials of algenpantucel-L are sufficient to support approval. In addition, there are multiple methods of statistical analysis that could be used to evaluate the data from our algenpantucel-L IMPRESS Phase 3 and other clinical trials, and the methods that we use, or that the FDA uses or permits us to use, may demonstrate lower, or no, statistical significance in achieving the applicable clinical trial endpoints, or may require an extended period of time to demonstrate statistical significance, if at all, as compared to other methods of statistical analysis that we could use.

The final results of our Phase 3 clinical trials of algenpantucel-L 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 algenpantucel-L. 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 completed testing of 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 completed to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of algenpantucel-L, 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 algenpantucel-L 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 algenpantucel-L to be approved as a marketable drug. Patients in our Phase 3 study who do not receive algenpantucel-L 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 algenpantucel-L have results which are better than the results predicted by the other large studies, we may not demonstrate a sufficient benefit from algenpantucel-L to allow or convince 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, which we may not be able to resolve or which may cause significant delays in development, will not arise in the future.

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, including post-approval 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 algenpantucel-L 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 the 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 algenpantucel-L IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) 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 algenpantucel-L IMPRESS 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 Biologics License Application, or BLA, 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, and any methods of data analysis that we may propose to use that are not specifically set forth in the SPA may be rejected by the FDA. 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 IMPRESS Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of algenpantucel-L 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 IMPRESS 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 are 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 IMPRESS 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 IMPRESS Phase 3 clinical trial, how it will view our analysis of such data and results or whether algenpantucel-L will receive any regulatory approvals as a result of the SPA agreement or the IMPRESS Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for algenpantucel-L 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 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. We are currently allocating significant resources to the development of an Ebola vaccine product candidate in accordance with our obligations under the Merck Agreement, and these efforts may ultimately prove unsuccessful or unprofitable, and may divert our resources from the development and commercialization of our other product candidates. 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. Furthermore, our resource allocation decisions, and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate 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, or 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:

- we may experience 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;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience 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;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- enrollment in and conduct of our clinical trials may be adversely affected by competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- we may experience 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 our product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize our 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, or, in the case of our Ebola vaccine product candidate, healthy volunteers willing to participate in the trials. 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;
- in the case of Ebola vaccine product candidate trials, changes in media coverage of the current Ebola epidemic;
- 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.

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. We may experience difficulty enrolling healthy volunteers in our current or any future clinical trials for our Ebola vaccine product candidate due to the perceived risks of receiving the Ebola vaccine product candidate, a decrease or increase in public attention on Ebola or other factors. 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.

In addition, 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.

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 in future years.

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.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, which may result in greater costs and a longer timeframe for regulatory approval than we estimate, yet we will receive limited revenues, if any, from any future sales of our Ebola vaccine product candidate.

Under the Merck Agreement, we have ongoing obligations related to the development of our Ebola vaccine product candidate, including obligations related to clinical trials, government contracting and licensing of the vaccine technology, which may cause us to incur costs or losses materially larger than we expect. However, because we have exclusively licensed the right to research, develop, manufacture and distribute our Ebola vaccine product candidate to Merck and we are only entitled to certain royalty and other payments under the Merck Agreement, we will receive limited revenues, if any, if we or Merck are successful in developing and commercializing our Ebola vaccine product candidate.

The time and cost of product development and the timeframe for regulatory approval of our Ebola vaccine product candidate, if any, are uncertain and may be longer and more costly than we estimate. Our Ebola vaccine product candidate is a live virus based on vesicular stomatitis virus (VSV). There are no commercial vaccines based upon this virus, and unforeseen problems related to the use of our live virus vaccine may prevent or materially increase costs and delays of further development or approval of our Ebola vaccine product candidate. There may be unknown safety risks associated with the vaccine and regulatory agencies such as the FDA may require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by the vaccine.

Our and Merck's research and development efforts on our Ebola vaccine product candidate use live virus vaccine technology, and our and Merck's successful development and commercialization of our Ebola vaccine product candidate depends on the costs and timing of development, including costs and timeframes for regulatory approval. There can be no assurance that any development problems we or others researching this virus vaccine may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

Public perception of vaccine safety issues, including adoption of novel vaccines based upon VSV, may adversely influence willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe, and of patients to receive, novel vaccines. For example, our Ebola vaccine product candidate is currently being developed for prevention of, and may later be developed for treatment of patients infected with, Ebola, and public aversion to vaccines for Ebola or vaccines in general may adversely influence later stage clinical trials of this product candidate or, if approved, its commercial success.

Even if approved, a number of factors may adversely affect commercial sales. Lack of familiarity with the viral vaccine and potential adverse events associated with vaccination may adversely affect physician and patient perception and uptake of our potential product. Furthermore, there are no assurances that the vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad. If our Ebola vaccine product candidate eventually is approved and sold commercially, we will receive limited revenues under the Merck Agreement.

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, indoximod 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, indoximod and other product candidates for additional indications.

Some of our product candidates have been or in the future may be studied in clinical trials co-sponsored by organizations or agencies other than us, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

Our indoximod product candidate has been studied in two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying our indoximod product candidate in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of our dorgenmeltucel-L (HyperAcute Melanoma) product candidate in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate is being studied in clinical trials in West Africa. We may 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, including follow-up with patients and ongoing collection of data after treatment, 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, indoximod, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We or our collaborators may not be able to obtain the labeling claims necessary or desirable for the promotion of any potential future products. We or our collaborators 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 or our collaborators that may be expensive and/or time consuming to fulfill. In addition, if we or others identify adverse side effects after any of our potential products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our potential products, additional clinical trials, changes in labeling of our potential products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our potential 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, which may include negotiating and entering into arrangements for third-party contract manufacturing in addition to the WuXi Agreement for some or all of our commercial manufacturing requirements. We plan to seek FDA approval for our production process simultaneously with seeking approval for the marketing and sale of algenpantucel-L. 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 could potentially be lower than if we market and sell any products that we develop ourselves.

We entered into the Genentech Agreement in October 2014 for the sales, marketing and distribution of NLG919, and we entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. If NLG919 or our Ebola vaccine product candidate are approved by regulators for marketing and sale, Genentech or Merck may be unsuccessful in their efforts to commercialize NLG919 or our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

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, including to co-promote NLG919 under the Genentech Agreement. 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 collaborators 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 collaborate 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. and Dr. Nicholas N. Vahanian. The loss of either of their 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 product development and marketing and sales activities, if any, 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. Our personnel needs will be further exacerbated as a result of our efforts to develop our Ebola vaccine product candidate under the Merck Agreement. 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 most significant facilities are located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. 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. In June 2014, we entered into the WuXi Agreement, under which we granted WuXi a non-exclusive right to use certain of our starting materials and confidential information for the commercial manufacturing of cell material for the production of algenpantucel-L. We will incur significant expense under the WuXi Agreement, and our commercial relationship with WuXi may not result in the manufacture of algenpantucel-L to the required quality standards or in quantities or at a cost that allows any future commercial sales to be profitable or commercially viable for many reasons, including the following:

- the FDA may not approve the facilities used by, or the manufacturing processes developed by, WuXi, or the FDA may impose additional requirements that result in unforeseen expense or delay;
- we have no experience managing relationships with commercial manufacturing organizations, and we may make decisions in connection with our relationship with WuXi that result in unforeseen delays, expenses or other difficulties, or that later prove to be less advantageous than other decisions we could have made;
- we or WuXi may encounter unforeseen difficulties in attempting to manufacture biological materials related to algenpantucel-L at a larger scale than we have previously attempted;
- WuXi may not be able to devote sufficient resources or facilities to manufacture cell materials in the quantities we may require;
- the manufacturing processes may produce low or variable quality or quantities of manufactured cell materials, and we may expend considerable resources attempting to identify or remedy factors causing such problems, or we may not be able to identify or remedy such factors;
- WuXi is currently our sole contract manufacturer for cell materials, and any unforeseen difficulties or work slow down or stoppage resulting from economic, labor, governmental, political or environmental factors, among others, may result in increased costs or delay, or a reduction or elimination of WuXi's ability to manufacture cell material for algenpantucel-L; and
- the FDA may not approve algenpantucel-L for the treatment of patients with pancreatic cancer, or any subset of such patients, which would not relieve our obligation for certain costs under the WuXi Agreement.

We may develop additional or alternative manufacturing capacity by expanding our current facilities, by entering into additional third-party contract manufacturing arrangements, or by some combination of the foregoing. Expanding our current facilities 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. Contracting for additional third-party commercial

manufacturing would require expertise and qualified personnel to manage the added complexity of such additional relationships and regulatory compliance at multiple manufacturing sites operated by different third-parties and may further increase our expenses related to, and decrease our direct control over, procuring a sufficient supply of our product candidates for commercial sale.

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 WuXi or 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. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms 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 each BLA and each 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 us, our existing contract manufacturers and those we may engage in the future, and Genentech and Merck in their respective capacities as our licensees, 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 any of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any of our product candidates 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. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for our Ebola vaccine product candidate, we are or will be subject to additional risks including the need to comply with export and import regulations.

Our costs for the manufacture and clinical development of our Ebola vaccine product candidate may exceed our current or any future funding for our Ebola vaccine product candidate development efforts.

We have entered into certain commercial manufacturing and clinical trial management agreements for our Ebola vaccine product candidate, and we expect to enter into additional agreements and incur additional costs related to our obligations under the Merck Agreement and our agreements with government agencies that are providing funding to us for the development our Ebola vaccine product candidate. We believe that the total costs that we are likely to incur to fulfill our contractual obligations under agreements with third parties for the development of our Ebola vaccine product candidate may exceed our total amount of funding from all sources for such activities. In addition, we are likely to incur operating expenses related to our Ebola vaccine product candidate in addition to our direct contractual costs of administering our Phase 1 Ebola vaccine product candidate clinical trial. Our failure to obtain sufficient grant or other funding for our Ebola vaccine development efforts will not relieve us of our obligations under our current or future contract manufacturing and other agreements for the Ebola vaccine product candidate.

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. The loss of any of these manufacturers, some of which are our only current source for components of our product candidates, or delays or problems in the supply or manufacture of components of our product candidates, could materially and adversely affect our business, financial condition and results of operations.

We intend to rely on contract manufacturers or strategic partners for all of product candidates, including algenpantucel-L, for commercial sale if any are approved for sale. In addition, we currently rely on contract manufacturers for supply of our Ebola vaccine product candidate for preclinical and clinical studies. 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 of or finished HyperAcute product candidates, indoximod or our Ebola vaccine product candidate. 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, or the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to manufacture products at commercial scale or to negotiate and enter into relationships with third-party contract manufacturers. Any prolonged delay or interruption in the operations of our facilities or our current or future 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 international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by 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 current or future 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 replicate all biological cells for clinical trials of our product candidates internally and utilize a single manufacturing site to manufacture our clinical product candidates other than our Ebola vaccine product candidate. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture product candidates for clinical testing and would result in increased costs and losses.

We have thus far elected to replicate all biological cells for our product candidates other than our Ebola vaccine product candidate for clinical testing 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 product candidates. 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 or may be impossible to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture product candidates 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 have experienced bacterial and mycoplasm contaminations in lots produced at our facilities, and we destroyed the contaminated lots and certain overlapping lots. We may experience additional contaminated lots at our facilities, and we will destroy any contaminated lots that we detect, which could result in significant delay or additional expense in our operations.

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 our current supplier is unable to continue supplying the component for our clinical trials,or to supply the component at quantities insufficient for commercial sale, we may need to utilize an alternative 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.

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 primary 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 $10.8 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.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

Risks Relating to Regulation of Our Industry

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

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. 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 any of our product candidates that may be approved for marketing.

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;
- 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;
- a licensure framework for follow-on biologic products, also known as biosimilars;
- 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 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.

At this time, it remains unclear the full effect that the PPACA would have on our business. 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.

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.

Financial Risks

Despite our profitability in 2014, we have a history of net losses. We expect to incur net losses in 2015 and to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014 primarily as a result of an upfront payment under the Genentech Agreement, as well as an upfront payment under the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. Any future milestone payments under the Genentech Agreement depend on our achievement of specific milestones, and any royalties depend on successful commercialization of NLG919 or other licensed products. The potential milestone and royalty payments under the Genentech Agreement are highly uncertain and dependent on many factors outside of our control related to possible future clinical trials and commercialization. We do not expect any milestone or royalty payments under these or other agreements, if any, to be sufficient to make us profitable in future years. As a result of these and other factors, we do not expect to be profitable in the year ending December 31, 2015. If we had not received the upfront payments under the Genentech Agreement and the Merck Agreement, we would have incurred a net loss for

the year ended December 31, 2014. In addition, we have incurred significant net losses in each year since our inception prior to the year ended December 31, 2014, including net losses of $31.2 million and $23.3 million for the years ended December 31, 2013 and 2012, respectively. Despite our net income for the year ended December 31, 2014, we had an accumulated deficit of $33.1 million as of December 31, 2014. Our losses have resulted principally from costs incurred in our research activities. We anticipate that our operating losses will substantially increase over the next several years as we expand both our commercialization activities and our discovery and research activities.

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 in future years 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 may 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 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, either internally or through collaborations with third parties. 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 collaborations.

We anticipate that we will continue to generate significant losses in the future 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 our existing cash and cash equivalents and certificates of deposit will allow us to fund our operating plan through the end of 2015. 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 approximately $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 collaborators, 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.

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, primarily in the form of forgivable loans, from state and local governments. We have also received significant financial assistance, primarily in the form of grants and contracts, from federal agencies to support our infectious disease research. 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 have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. 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.

Changes in our effective income tax rate could adversely affect our results of operations in the future.

As a result of our profitability for the year ended December 31, 2014, we were subject to income taxes, and we may become subject to income taxes in future years in the United States or foreign jurisdictions. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates, our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

Risks Relating to Competition

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.

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.

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 (sipuleucel-T) 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. Trials of these product candidates target many different cancer types. Of this universe, several large public biopharmaceutical companies are developing or have commercialized cancer immunotherapy products, including Genentech, Bristol-Myers Squibb Company, Dendreon Corporation, GlaxoSmithKline plc, MedImmune/Aztra Zenaca, Merck & Co., Inc., Merck KGaA and Sanofi-Aventis. There are numerous immunotherapeutic approaches to cancer immunotherapy product development, 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.

There are no anti-cancer drugs currently approved by the FDA for patients with resected pancreatic cancer. However, there are several companies actively marketing anti-cancer drugs indicated for patients with advanced pancreatic cancer including: Celgene Corporation with Abraxane (nab-paclitaxel) and Genentech/Astellas with Tarceva (erlotonib). Additionally, there are numerous generic drugs approved for advanced disease including: gemcitabine, fluorouracil and mytomycin C. In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer.

There are numerous companies actively marketing FDA approved drugs for patients with Non-Small Cell Lung Cancer, or NSCLC, including Celgene with Abraxane (nab-paclitaxel), Genentech/Roche with Avastin (bevacizumab), Eli Lilly with Alimta (premetrexed), Astellas/Genentech with Tarceva (erlotinib) and Pfizer with Xalkori (crizotinib). In March 2015, Bristol-Myer Squibb received FDA approval for Opdivo (nivolumab), the first immunotherapy drug approved for NSCLC. Additionally, there a number of generic drugs with FDA approval for use in NSCLC, including cisplatin, docetaxel, paclitaxel, gemcitabine, vinorelbine and methotrexate. In addition, there are a number of companies with active clinical trials ongoing in NSCLC.

Research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, indoximod, NLG919 or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, 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.

Our infectious disease product candidates face significant competition for United States government funding for both development and procurement of vaccines against infectious diseases, medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Public and private

biopharmaceutical companies, academic institutions, government agencies, private research organizations and public research organizations are conducting research and filing patents toward commercialization of products. In particular, given the widespread media attention on the current Ebola epidemic, there are competitive efforts by public and private entities to develop an Ebola vaccine as fast as possible, including by GlaxoSmithKline. Those other entities may develop Ebola vaccines that are more effective than any we may develop in collaboration with Merck, or may develop an Ebola vaccine at a lower cost or earlier than we or Merck are able to develop any Ebola vaccine, or they may be more successful at commercializing an Ebola vaccine. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our Ebola vaccine development efforts. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to infectious disease or biodefense products.

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

Even if our 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 future 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, as well as our strategic partners and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Genentech and Merck are responsible for clinical trials of NLG919 and our Ebola vaccine product candidate, respectively, 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.

Finally, we are dependent on Genentech and Merck for the development of the product candidates that are the subject of the Genentech Agreement and the Merck Agreement, respectively. If either company does not succeed in advancing any product candidate to final approval, such failure could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, or we enter into collaborations that are ultimately unsuccessful, we may be unable to commercialize any potential product effectively or at all.

To successfully commercialize any potential product, 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, as we did in the case of the Genentech Agreement and the Merck Agreement. 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 subject product candidates, the costs and complexities of manufacturing and delivering the potential product 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 a potential product is necessary or beneficial and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the potential product 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, including the Genentech Agreement to commercialize NLG919 and the Merck Agreement to commercialize our Ebola vaccine product candidate, 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 subject potential product;
- 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 potential product 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 potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the potential product.

Under the Genentech Agreement, the Merck Agreement and any future collaboration for our 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 potential product may have the right to terminate the collaboration at its discretion and, for example, Genentech does have the right to terminate the Genentech Agreement for any reason after October 16, 2016 and Merck does have the right to terminate the Merck Agreement for any reason upon a specified advance notice period. 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 potential product 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 may explore strategic collaborations that may never materialize or may fail.

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

Under the Genentech Agreement and the Merck Agreement, we are required, and we may be required under future collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

Our collaborations, including any future strategic collaborations 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;
- other than under the Genentech Agreement and the Merck Agreement, 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 collaborators 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 collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators 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 collaborators 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 collaborators may experience financial difficulties;
- strategic collaborators 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 collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators 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.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor to file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party 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, marketing and commercial sale 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. In addition, healthy volunteers in our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidate, and may initiate legal action against us.

We currently carry clinical trial liability insurance in the amount of $5 million in the aggregate for claims related to our drug candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. 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 future products by us or our collaborators.

On December 9, 2014, the United States Department of Health and Human Services declared our Ebola vaccine product candidate covered under the Public Readiness and Emergency Preparedness Act. This declaration provides immunity under U.S. law against legal claims related to the manufacturing, testing, development, distribution and administration of our vaccine candidate. It does not generally provide immunity for a claim brought in a court outside the United States.

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 Quarterly Report on Form 10-Q, 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.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

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 of this this Annual Report on Form 10-K and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, 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 IMPRESS clinical trial of our algenpantucel-L, 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;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- 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 collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived successes or failures, of our collaborators, including Genentech and Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, on cancer and cancer treatment, on the Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- 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, and 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 December 31, 2014, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 52.7% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after December 31, 2014. 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 may be distributed and subsequently voted.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This 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 in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Certain holders of outstanding shares of our common stock that 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.

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

As a public company, we incur significant legal, accounting and other expenses to comply with 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 SEC and The NASDAQ Stock Market, or NASDAQ. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes 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 devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may 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 are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude 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 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.

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 securities held by existing investors.

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. A Section 382 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 Section 382 ownership change analyses, we believe that, from its inception through December 31, 2014, NewLink experienced Section 382 ownership changes in September 2001 and March 2003 and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited NewLink's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of NewLink and our subsidiary.

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. 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We conduct our primary operations at leased facilities described below.

Location	Operations Conducted	Approximate Square Feet	Lease Expiration Date
Ames, Iowa	Executive offices, research and development, and manufacturing	50,000	2020
Austin, Texas	Commercial and administrative offices	9,898	2016
Ankeny, Iowa	Packaging and distribution	47,250	2017
Devens, Massachusetts	Administrative offices	1,310	2015

We believe that our administrative office space is adequate to meet our needs for the foreseeable future. We also believe that our research and development facilities, our warehousing facilities and our manufacturing facility, together with third party manufacturing facilities, will be adequate for our on-going activities.

Item 3. LEGAL PROCEEDINGS

None.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASE OF EQUITY SECURITIES

Our common stock is quoted on The Nasdaq Stock Market, LLC under the symbol "NLNK." The following table sets forth the range of high and low sales prices for our common stock on The Nasdaq Stock Market, LLC for the periods indicated since November 11, 2011.

	High	Low
Fiscal 2014		
First Quarter	$ 53.48	$ 20.99
Second Quarter	29.54	18.28
Third Quarter	29.48	20.01
Fourth Quarter	42.00	17.32
Fiscal 2013		
First Quarter	$ 12.70	$ 11.40
Second Quarter	22.56	11.27
Third Quarter	20.16	15.78
Fourth Quarter	23.50	16.04

As of March 10, 2015, we had 113 stockholders of record of our common stock.

Dividend Policy

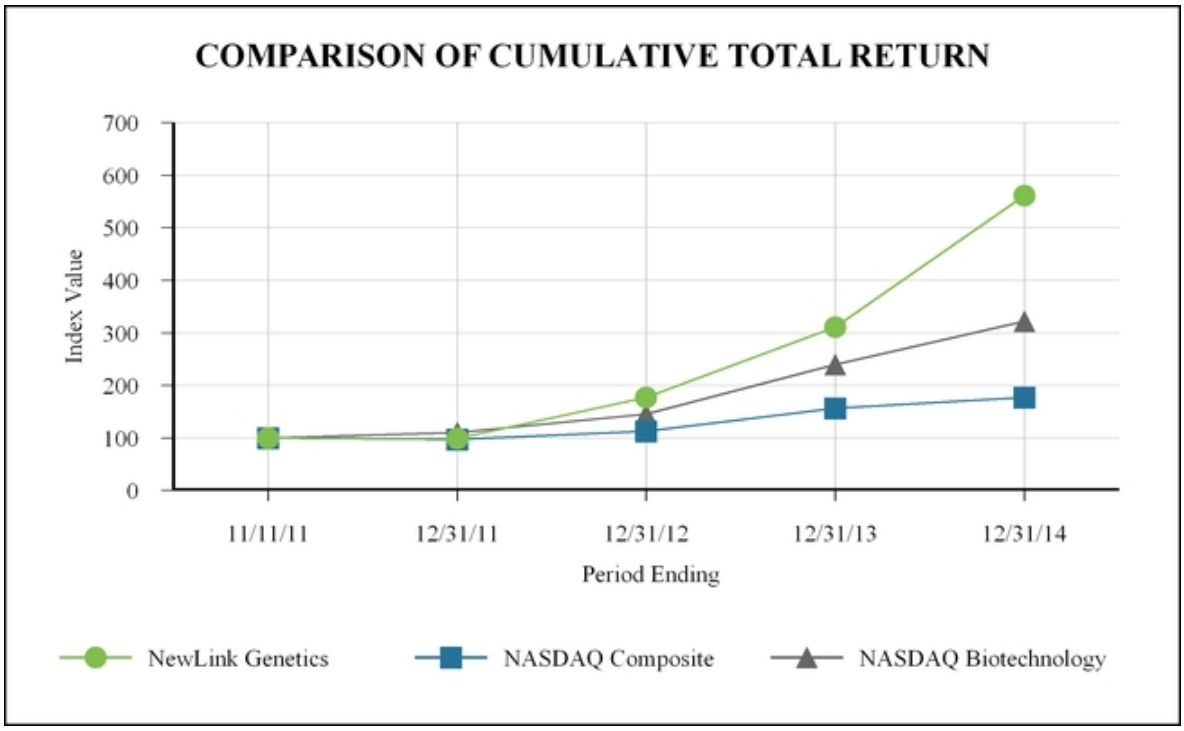
We have never paid cash dividends. We do not expect to declare or pay any cash dividends on our common stock in the near future. We intend to retain all earnings, if any, to invest in our operations. The payment of future dividends is within the discretion of our board of directors and will depend upon our future earnings, if any, our capital requirements, financial condition and other relevant factors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated by reference to Item 12 of Part III of the Annual Report on Form 10-K.

Our Stock Performance

The following graph compares cumulative total return of our Common Stock with the cumulative total return of (i) the NASDAQ Stock Market-United States, and (ii) the NASDAQ Biotechnology Index. The graph assumes (a) $100 was invested on November 11, 2011 in our Common Stock, the stocks comprising the NASDAQ Stock Market-United States and the stocks comprising the NASDAQ Biotechnology Index, and (b) the reinvestment of dividends. The comparisons shown in the graph are based on historical data and the stock price performance shown in the graph is not necessarily indicative of, or intended to forecast, future performance of our stock.



* $100 invested on November 11, 2011 in stock or index, including reinvestment of dividends.

Cumulative Total Return

	11/11/2011	12/31/2011	12/31/2012	12/31/2013	12/31/2014
NewLink Genetics Corporation	$100	$99	$177	$311	$561
NASDAQ Composite	$100	$97	$113	$156	$177
NASDAQ Biotechnology	$100	$110	$145	$240	$322

Date*	Transaction Type	Closing Price**	Beginning No. Of Shares***	Dividend per Share	Dividend Paid	Shares Reinvested	Ending Shares	Cum. Total Return
11-Nov-11	Begin	$7.08	14.124				14.124	$100.0
31-Dec-11	Year End	$7.04	14.124				14.124	$99.4
31-Dec-12	Year End	$12.50	14.124				14.124	$176.6
31-Dec-13	Year End	$22.01	14.124				14.124	$310.9
31-Dec-14	Year End	$39.75	14.124				14.124	$561.4

* Specified ending dates are ex-dividends dates.
** All Closing Prices and Dividends are adjusted for stock splits and stock dividends.
*** 'Begin Shares' based on $100 investment.

Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities

During the month of January, 2014 the Company repurchased 8,493 shares of its common stock at an average price of $21.38 per share. During the month of September 2014 the Company repurchased 1,900 shares of its common stock at an average price of $21.42 per share.

Use of Proceeds

Not applicable.

Item 6. SELECTED FINANCIAL DATA

You should read the following selected consolidated financial data together with our financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this annual report.

We derived the annual consolidated financial data from our audited financial statements, the last three years of which are included elsewhere in this Annual Report on Form 10-K. We derived the summary statement of operations data for the years ended December 31, 2010 and 2011 and the balance sheet data as of December 31, 2010, 2011 and 2012 from our audited financial statements not included in this annual report.

Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except per share data)				
Statement of operations data:					
Grant revenue	$ 6,642	$ 1,093	$ 1,687	$ 1,872	$ 2,079
Licensing revenue	165,950	—	—	—	—
Total operating revenue	172,592	1,093	1,687	1,872	2,079
Operating expenses:					
Research and development	35,691	22,713	17,838	14,255	12,666
General and administrative	19,328	9,521	7,108	5,679	6,074
Total operating expenses	55,019	32,234	24,946	19,934	18,740
Income (loss) from operations	117,573	(31,141)	(23,259)	(18,062)	(16,661)
Other income and expense:					
Miscellaneous income (expense)	—	112	(38)	5	71
Interest income	86	12	14	11	75
Interest expense	(26)	(33)	(38)	(42)	(47)
Other income (expense), net	60	91	(62)	(26)	99
Net income (loss) before taxes	117,633	(31,050)	(23,321)	(18,088)	(16,562)
Income tax expense	(14,775)	(130)	—	—	—
Net income (loss)	102,858	(31,180)	(23,321)	(18,088)	(16,562)
Less net loss attributable to noncontrolling interest	—	—	—	1	349
Net income (loss) attributable to NewLink stockholders	$ 102,858	$ (31,180)	$ (23,321)	$ (18,087)	$ (16,213)
Basic earnings (loss) per share	$ 3.69	$ (1.23)	$ (1.12)	$ (2.98)	$ (4.84)
Diluted earnings (loss) per share	$ 3.32	$ (1.23)	$ (1.12)	$ (2.98)	$ (4.84)
Basic average shares outstanding	27,839	25,275	20,779	6,065	3,352
Diluted average shares outstanding	31,025	25,275	20,779	6,065	3,352

	As of December 31,				
	2014	2013	2012	2011	2010
	(in thousands)				
Balance sheet data: (1)					
Cash, cash equivalents, and certificates of deposit	$ 202,797	$ 61,540	$ 21,744	$ 41,980	$ 12,841
Working capital	205,442	60,094	20,470	32,124	11,377
Total assets	238,062	70,557	29,429	48,379	20,078
Royalty obligations, notes payable and obligations under capital leases	7,133	7,222	7,382	7,156	7,294
Convertible preferred stock	—	—	—	—	62,775
Accumulated deficit	(33,119)	(135,977)	(104,797)	(81,476)	(63,389)
Total stockholders' equity (deficit)	$ 203,777	$ 58,327	$ 17,927	$ 36,773	$ (52,019)

(1) From January 1, 2015 through March 4, 2015, we sold 329,402 shares of common stock raising a total of $13.6 million in net proceeds. The data presented above does not include these proceeds.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. Our portfolio includes biologic and small-molecule immunotherapy product candidates intended to treat a wide range of oncology indications. Our lead product candidate, algenpantucel-L cancer immunotherapy, or HyperAcute Pancreas, is being studied in two Phase 3 clinical trials; one 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, and one in patients with locally advanced pancreatic cancer. We initiated these trials based on encouraging Phase 2 data that suggest 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 and Orphan Medicinal Product designation for this product candidate from the European Commission. The primary endpoint for our IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 trial with algenpantucel-L for patients with surgically-resected pancreatic cancer is overall survival. Our additional product candidates in clinical development include tergenpumatucel-L, or HyperAcute Lung, dorgenmeltucel-L, or HyperAcute Melanoma, our HyperAcute Prostate cancer immunotherapy, or HyperAcute Prostate, our HyperAcute Renal cancer immunotherapy, or HyperAcute Renal, 1-methyl-D-tryptophan (D-IMT), or indoximod, our proprietary IDO pathway inhibitor product candidate, and NLG919, an IDO pathway inhibitor licensed to Genentech. To date, our HyperAcute product candidates have been dosed in more than 700 cancer patients, either as a monotherapy or in combination with other therapies, and have demonstrated a favorable safety profile. We believe that our immunotherapeutic technologies have the potential to lead to multiple product candidates, targeting a wide range of oncologic indications that can be used either alone or in combination with the other therapies. In addition, we have significant technology to address infectious diseases, including our rVSV-EBOV vaccine candidate for the Ebola virus.

We have incurred significant losses since our inception. Our profits to date have been primarily the result of large payments received in connection with licensing transactions. In the absence of such transactions, which we do not expect in 2015, we expect our losses to increase over the next several years as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval. We generated net income of $102.9 million, and incurred net losses of $31.2 million and $23.3 million for the years ended December 31, 2014, 2013, and 2012, respectively.

On October 25, 2011, we filed a Certificate of Amendment of the Restated Certificate of Incorporation with the Secretary of State of Delaware effecting a 2.1-for-one reverse split of our Common Stock. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented.

Initial Public Offering and Subsequent Equity Offerings

On November 16, 2011, we completed our initial public offering, or IPO, raising a total of $37.6 million in net proceeds after deducting underwriting discounts and commissions of $3.0 million and offering expenses of $2.9 million.

On February 4, 2013, we completed a follow-on public offering, raising a total of $49.0 million after deducting $3.1 million in underwriter discounts and commissions and offering expenses of $300,000.

We entered into a Sales Agreement, with Cantor Fitzgerald & Co., dated as of September 5, 2013, under which we may sell up to $60.0 million in shares of our common stock in one or more placements at prevailing market prices for our common stock, or the ATM Offering. Any such sales would be effected pursuant to our registration statement on Form S-3 (333-185721), declared effective by the Securities and Exchange Commission, or SEC, on January 4, 2013. As of December 31, 2014, we had sold 1,833,838 shares of common stock raising a total of $45.2 million in net proceeds under the ATM Offering. Subsequent to December 31, 2014 and through March 4, 2015, we sold an additional 329,402 shares of common stock under the ATM Offering raising an additional $13.6 million in net proceeds.

Financial Overview

Revenues

We have never earned revenue from commercial sales of any drugs. We earned net income of $102.9 million for the year ended December 31, 2014, primarily as a result of entering into two license and collaboration agreements during 2014.

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, milestones, research and development and royalty payments in connection with strategic collaborations or government contracts, 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 research 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. For the years ended December 31, 2014, 2013 and 2012 we have incurred $35.7 million, $22.7 million, and $17.8 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,		
	2014	2013	2012
HyperAcute immunotherapy technology	$ 21,681	$ 16,241	$ 11,957
IDO pathway inhibitor technology	6,962	4,772	4,153
Other research and development	7,048	1,700	1,728
Total research and development expenses	$ 35,691	$ 22,713	$ 17,838

Research and Development Expenses by Category
(In thousands)

	Years Ended December 31,		
	2014	2013	2012
Compensation	$ 13,951	$ 9,273	$ 7,619
Equipment, supplies and occupancy	5,859	5,846	4,932
Outside clinical and other	15,881	7,594	5,287
Total research and development expenses	$ 35,691	$ 22,713	$ 17,838

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 compensation;
- 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 expect to incur increased expenses related to the planned sales and marketing of our product candidates, which may include recruiting a specialty sales force, 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 our offerings 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 notes payable and obligations under capital leases.

Tax Loss Carryforwards

The valuation allowance for deferred tax assets as of December 31, 2014 and 2013 was $7.1 million and $25.2 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2014 and 2013 was a decrease of $18.1 and an increase of $2.0 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, 2014 and 2013, due to the uncertainty of future recoverability.

As of December 31, 2014 and December 31, 2013, we had federal net operating loss carryforwards of $2.3 million and $88.4 million and federal research credit carryforwards of $120,000 and $4.3 million, respectively, that expire at various dates from 2026 through 2031. We used $89.1 million in net operating loss and federal research credit carryforwards in 2014. 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 analysis, we believe that, from our inception through December 31, 2014, we experienced Section 382 ownership changes in September 2001 and March 2003 and our subsidiary experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of us and our subsidiary.

Even if another ownership change has not occurred, 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.

Income tax expense was $14.8 million, $130,000, and $0 for the years ended December 31, 2014, 2013 and 2012, respectively. 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.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our consolidated financial statements in accordance with United States generally accepted accounting principles, or GAAP. 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. We have reviewed our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

While our significant accounting policies are described in more detail in note 2 to our consolidated financial statements included later in this annual report, we believe the following accounting policies to be critical 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 expenses, 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.

Share-Based Compensation

We are required to estimate the grant-date fair value of stock options, stock awards and restricted stock issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each award granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. 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 calculate the fair value of the award on the grant date, which is the date the award is authorized by the Board of Directors or Chief Executive Officer and the employee has an understanding of the terms of the award.

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 measured each period until vesting, and is recognized through the earlier of the vesting of the award or completion of services by the nonemployee.

We recorded noncash share-based compensation expense for employee and nonemployee stock options and restricted stock awards of $8.6 million, $4.4 million, and $3.2 million during 2014, 2013 and 2012, respectively. As of December 31, 2014, the total compensation cost related to nonvested option awards and restricted stock awards not yet recognized was $18.8 million and the weighted average period over which it is expected to be recognized was 3 years. We expect to continue to grant stock options and restricted stock awards in the future, which will increase our share-based compensation expense in future periods. If any of the assumptions used in the Black-Scholes model change significantly, share-based compensation expense for new awards or awards to nonemployees may differ materially in the future from that recorded in the current period for awards previously granted.

The following table summarizes our assumptions used in the Black-Scholes model for option grants during the last three years:

Black-Scholes Model Assumptions

	Years Ended December 31,		
	2014	2013	2012
Exercise price	$20.26-$46.76	$11.79-$22.61	$6.87-$15.16
Risk-free interest rate	1.73%-2.24%	.89%-2.14%	.98%-2.05%
Expected dividend yield	—	—	—
Expected volatility	57.4%-68.3%	61.4%-67.3%	63.0%-73.6%
Expected term (in years)	6.0-7.0	4.8-7.0	5.8-7.0

Exercise Price. Subsequent to the IPO, options have been granted with an exercise price of the fair value of our common stock on the date of grant based on the current market price.

Expected Volatility. We estimate future expected volatility for each stock option valuation utilizing volatility rates of similar publicly traded companies considered to be in the same peer group. We use a combination of our own data and peer group data to compute our volatility and will continue to do so until we have sufficient information to rely solely on our own volatility. 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. We use historical exercise and option expiration data to estimate the expected term assumption for the Black-Scholes grant-date valuation. We believe this historical data is currently the best estimate of the expected term of awards.

Risk-Free Interest Rate. We use the average yield on current U.S. 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 share-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 share-based award over its vesting period will only be for those shares that actually vest.

Common Stock Fair Value. The fair value of the common stock was determined by the Board of Directors in good faith until November 16, 2011, when our common stock initiated trading on the NASDAQ Stock Market. Following that date, the fair value of the common stock has been the quoted market price as listed on the public exchange.

Based on the December 31, 2014 price of $39.75 per share, the intrinsic value of stock options outstanding at December 31, 2014, was $154.9 million, of which $126.0 million and $28.9 million related to stock options that were vested and unvested, respectively, at that date.

Revenue Recognition

We recognize revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or as services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

We follow ASC 605-25, Revenue Recognition - Multiple-Element Arrangements and ASC 808, Collaborative Arrangements , if applicable, to determine the recognition of revenue under our license and collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) clinical supply, and/or (iv) participation on joint research or joint steering committees. The payments we may receive under these arrangements

typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. If management believes that the license to our intellectual property has stand-alone value, we generally recognize revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, we would recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. When the performance period is not specifically identifiable from the agreement, we would estimate the performance period based upon provisions contained within the agreement, such as the duration of the research or development term.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of collaborator's performance are recognized when earned.

See Note 5 – License and Research Collaboration Agreements to the accompanying audited financial statements included elsewhere in this Annual Report on Form 10-K for further information.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013

Revenues. Revenues for the year ended December 31, 2014 were $172.6 million, increasing from $1.1 million for the same period in 2013. The increase in revenue of $171.5 million was due to an increase of $166.0 million in licensing revenue, and a $5.5 million increase in grant revenue under various government contracts.

Research and Development Expenses. Research and development expenses for the year ended December 31, 2014 were $35.7 million, increasing from $22.7 million for the same period in 2013. The $13.0 million increase was due to an $8.3 million increase in outside clinical and other expenses including contract development costs for NLG919, contract manufacturing costs for indoximod and the Ebola vaccine product candidate, consulting fees, and direct development expenses for our clinical trial activities, accompanied by a $4.7 million increase in personnel-related expenses due to increased staffing levels and compensation increases.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2014 were $19.3 million, increasing from $9.5 million for the same period in 2013. The $9.8 million increase was due to a $5.8 million increase in other costs including legal and consulting fees, travel, and licensing expense, accompanied by a $4.0 million increase in personnel-related expenses due to increased staffing levels and compensation increases, which includes $1.7 million in share-

based compensation resulting from the vesting in full of one employee's options upon the employee's termination during the year ended December 31, 2014.

Income tax expense. Income tax expense for the year ended December 31, 2014 was $14.8 million increasing from $130,000 for the same period in 2013. The increase was primarily due to an increase of $166.0 million in licensing revenue offset by increases in operating expense in 2014.

Net Income (Loss). Net income for the year ended December 31, 2014 was $102.9 million, increasing from a net loss of $31.2 million for the same period in 2013 primarily due to an increase in licensing revenue, offset by an increase in operating expenses of $22.8 million and income tax expense of $14.6 million. The diluted average shares outstanding for 2014 were 31.0 million, resulting in diluted earnings per share of $3.32, as compared to 25.3 million and $1.23 diluted loss per share for 2013. The increase in the number of diluted average shares outstanding was primarily attributable to shares issued in our ATM Offering during the first quarter of 2014.

Comparison of the Years Ended December 31, 2013 and 2012

Revenues. Revenues for the twelve months ended December 31, 2013 were $1.1 million, decreasing from $1.7 million for the same period in 2012. The decrease in revenue of $594,000 was due to a decrease in billings and under various government contracts and grants.

Research and Development Expenses. Research and development expenses for the twelve months ended December 31, 2013 were $22.7 million, increasing from $17.8 million for the same period in 2012. The $4.9 million increase was due to a $2.3 million increase in outside clinical and other expenses including contract development costs for NLG919, contract manufacturing costs for indoximod and direct development expenses for our clinical trial activities, accompanied by a $1.6 million increase in personnel-related expenses due to increased staffing levels and compensation increases and a $914,000 increase in equipment, supplies and occupancy costs to support our expanding clinical trials.

General and Administrative Expenses. General and administrative expenses for the twelve months ended December 31, 2013 were $9.5 million, increasing from $7.1 million for the same period in 2012. The $2.4 million increase was due to a $1.3 million increase in other costs including consulting fees, director's and officer's insurance and software subscription fees, accompanied by a $1.1 million increase in personnel-related expenses due to increased staffing levels and compensation increases and a $21,000 increase in equipment, supplies and occupancy costs.

Income tax expense. Income tax expense for the year ended December 31, 2013 was $130,000, increasing from $0 for the same period in 2012. The increase was due to our Federal alternative minimum tax liability incurred in 2013.

Net Loss. Net loss for the year ended December 31, 2013 was $31.2 million, increasing from $23.3 million for the same period in 2012 due to a $4.9 million increase in research and development expense and a $2.4 million increase in general and administrative expense accompanied by a $594,000 decrease in revenue from contracts and grants. The weighted average common shares outstanding for 2013 were 25.3 million, resulting in a loss per share of $1.23, as compared to 20.8 million and $1.12 per share for 2012. The increase in the number of weighted average common shares outstanding was primarily attributable to shares issued in our public offering in February 2013, and to a lesser extent, shares issued in our ATM Offering during the fourth quarter of 2013.

Liquidity and Capital Resources

Before our IPO, we funded our operations principally through the private placement of equity securities, debt financing and interest income. As of December 31, 2014, 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.

Since our IPO, we have funded our operations principally through public offerings of common stock. On November 16, 2011, we received proceeds, net of offering costs, of $37.6 million from the issuance of 6,200,000 shares of common stock in our IPO. On February 4, 2013, we received proceeds, net of offering costs, of $49.0 million from the issuance of 4,600,000 shares of common stock in our follow-on offering. As of December 31, 2014, we had sold 1,833,838 shares of common stock in our ATM

Offering, raising a total of $45.2 million in net proceeds. Subsequent to December 31, 2014 and through March 4, 2015, we sold an additional 329,402 shares of common stock under the ATM Offering raising an additional $13.6 million in net proceeds.

In October 2014, we received an upfront payment of $150 million under the Genentech Agreement and in November 2014, we received an upfront payment of $30 million under the Merck Agreement.

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,		
	2014	2013	2012
Net cash provided by (used in) operating activities	$ 109,068	$ (25,818)	$ (20,471)
Net cash used in investing activities	(13,844)	(141)	(277)
Net cash provided by financing activities	33,889	67,000	1,508
Net increase (decrease) in cash and cash equivalents	$ 129,113	$ 41,041	$ (19,240)

For the year ended December 31, 2014, we generated cash of $109.1 million from our operating activities, and for the years ended December 31, 2013 and 2012, used cash of $25.8 million and $20.5 million, respectively, for our operating activities. For the year ended December 31, 2014, the source and use of cash in this period primarily resulted from our net income adjusted for non-cash items and changes in operating assets and liabilities. The net income for this period was primarily due to an increase in licensing income offset by increased operating and income tax expense. For the years ended December 2013 and 2012, the source and use of cash in these periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities.

For the years ended December 31, 2014, 2013 and 2012, our investing activities used cash of $13.8 million, $141,000 and $277,000, respectively. The cash used by investing activities in the year ended December 31, 2014 was due to $1.7 million in purchases of property and equipment offset by the combined net purchase of certificates of deposit for $12.1 million. The cash used by investing activities in the year ended December 31, 2013 was due to $1.4 million in purchases of property and equipment offset by the combined net sale of investments for $1.2 million. The cash used by investing activities in the year ended December 31, 2012 was due to $1.3 million in purchases of property and equipment offset by the combined net maturity of investments for $1.0 million.

For the years ended December 31, 2014, 2013 and 2012, our financing activities provided $33.9 million, $67.0 million and $1.5 million, respectively. The cash provided by financing activities in the year ended December 31, 2014 was primarily due to the sale and issuance of common stock for net proceeds of $29.9 million accompanied by $4.3 million from excess tax benefit from employee stock plan awards, offset by repurchase of common stock of $222,000 and net payments on long-term obligations of $89,000. The cash provided by financing activities in the year ended December 31, 2013 was primarily due to the sale and issuance of common stock for net proceeds of $67.2 million and offset by payments on long-term obligations of $215,000. The cash provided by financing activities in the year ended December 31, 2012 was primarily due to the sale and issuance of common stock for net proceeds of $1.3 million accompanied by proceeds on notes payable of $456,000 and offset by payments on long-term obligations of $229,000.

Obligations under our Royalty and Loan Agreements

March 2005 and March 2012 Iowa Economic Development Authority 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 were no principal or interest payments due until the completion date for the project. The agreement provided us with financial assistance for research and product development activities at our Iowa State University Research Park facility. Additionally, under the agreement, we were obligated to pay a minimum of 0.25% royalties on all gross revenues of any products that we bring to market with a cumulative maximum royalty amount due of $3.2 million. Substantially all of our assets were pledged to secure this loan. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, or the IEDA Agreement, with the Iowa Economic Development Authority, or the IEDA, as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement, the forgivable loan agreement between us and IEDA (as successor to IDED) was terminated and we were thereby released from the forgivable loan agreement's job creation, project expenditure, royalty and other requirements in exchange for agreeing to pay a royalty of 0.50% on all gross revenues of any products that we bring to market, with a cumulative maximum royalty obligation due of $6.8 million. Additionally, under the IEDA Agreement, the IEDA released its security interest in our assets. We are obligated to maintain our business substantially in the State of Iowa until the royalty obligation under the IEDA Agreement is satisfied.

September 2007 IDED High Quality Job Creation Program Tax Credit

In September 2007, we entered into a master contract and associated funding agreement, or the HQJC Agreement, with the IDED under its high quality job creation program. Under the HQJC Agreement, as amended, we received a tax credit of $414,000, which was refunded to us between March 2006 and October 2009. We fulfilled all of the job creation and investment requirements of the HQJC Agreement, as amended, on March 18, 2013.

2009 and 2012 Iowa State University Research Park Loans

In 2009, we executed a promissory note in favor of Iowa State University Research Park, or ISURP, in an original principal amount of $800,000, which is due in monthly installments through March 2018. The note represents amounts owed by us to ISURP for certain improvements that were made to facilities we lease 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 our 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. The balance outstanding under the 2009 note was $348,000 and $449,000 at December 31, 2014 and December 31, 2013, respectively.

In 2012, we executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September, 2020. The note represents amounts owed by us to ISURP for certain additional improvements that were made to facilities we lease 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 our 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. The balance outstanding under the 2012 note was $339,000 and $392,000 at December 31, 2014 and December 31, 2013, respectively.

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 original expected completion date for the project, which is March 10, 2015. This completion date was extended to March 10, 2016 in March 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 maintain at least 150 full-time positions located in Ames, Iowa as of March 10, 2016. The agreement also calls for us 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, 2016, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2016, we have failed to create or retain at least 150 full-time jobs in Ames, Iowa, we will be required to repay approximately $3,100 per job not created or retained following such date. As of December 31, 2014, $397,000 of the total $400,000 forgivable loan was advanced to us. 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 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, facilities, and distribution costs;
- the cost of manufacturing our product candidates and any products we commercialize, including out costs under the WuXi agreement, whether or not a sufficient quantity of cell material is manufactured under that agreement;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- 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 December 31, 2014:

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) (1)	$ 7,148	$ 576	$ 361	$ 161	$ 6,050
Operating lease obligations	4,177	1,322	1,957	850	48
Capital lease obligations	48	36	12	—	—
Total contractual cash obligations	$ 11,373	$ 1,934	$ 2,330	$ 1,011	$ 6,098

(1) Short and long-term debt includes an accrued royalty obligation of $6.0 million for which the timing of payment is uncertain. See section *"March 2005 and March 2012 Iowa Department of Economic Development Loan"* above.

Under the license agreements described below under the heading "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
Georgia Regents Research Institute	$2.8 million per licensed product
The Ohio State University	$2.75 million for first licensed product
Public Health Agency of Canada	C$205,000 per licensed product

(1) As defined below under the heading "Financial Obligations Related to Licensing and Development—In-Licensing Agreements".

We incurred expense of approximately $3.1 million, $88,000, and $255,000, under all of the in-licensing agreements for the years ended December 31, 2014, 2013, and 2012, respectively, which are listed below under the heading "Financial Obligations Related to Licensing and Development—In-licensing Agreements".

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, as amended December 30, 2013, 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 or 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 or our sublicensees 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, in addition to the royalties described above, 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. We have no obligation to pay fees to CIHS as a result of payments between us and our affiliates.

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 alpha-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 IDO 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.

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 IDO 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.

Georgia Regents Research Institute. We are a party to a License Agreement dated September 13, 2005, or the GRRI Agreement, with Georgia Regents Research Institute, or GRRI, which was formerly known as the Georgia Health Sciences University Research Institute, Inc. and the Medical College of Georgia Research Institute. The GRRI Agreement was amended on March 28, 2006, April 27, 2006, February 13, 2007, July 12, 2013 and July 10, 2014. The GRRI Agreement grants us, including our affiliates, an exclusive, worldwide license, under specified GRRI 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 GRRI 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 GRRI, we must pay to GRRI 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.

The Ohio State University License Agreement. We are a party to a license agreement dated June 28, 2013 with The Ohio State University, or OSU. This agreement grants us exclusive rights in the United States and its territories, in all fields of use, to patents related to pharmaceutical compositions and vaccines comprising antigens associated with L-Rhamnose and Forssman epitopes including patent application US 13/463,420, which is co-owned by us and OSU.

In consideration of the license grant, we were obligated to pay OSU specified license fees and are obligated to pay to OSU specified annual license maintenance fees, patent prosecution costs and maintenance costs, potential milestone payments in an aggregate amount up to approximately $2.75 million for the first licensed product, and royalties as a low single-digit percentage of net sales of the licensed products if a licensed product is commercialized, with minimum royalties for the first three years in which a licensed product generates revenue. In addition, if we grant a sublicense under this agreement, we must also pay to OSU a percentage of certain consideration received by us from the sublicensee. Under this agreement, we are obligated to use commercially reasonable efforts to develop and market the licensed products and to use commercially reasonable effort to achieve certain milestones by agreed-upon deadlines.

Public Health Agency of Canada Agreement. BPS is a party to the PHAC License, dated May 4, 2010. The PHAC License grants BPS a worldwide, personal, non-transferable, sole, revocable, royalty-bearing license for commercialization of specified PHAC 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, when 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, including a percentage of certain consideration received pursuant to such sublicense. BPS is obligated to use commercially reasonable efforts to develop and market the licensed products.

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.

Collaborative Agreements with Medical Institutions

We have entered into numerous agreements with various medical institutions for the performance of clinical trials for various products in the past. They typically require the payment of fees by us for the performance of the clinical trials and the maintenance of confidentiality as to the associated technology. We may enter into additional agreements in the future.

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 years ended December 31, 2014, 2013 and 2012, we incurred expenses related to the filing, maintenance, and initiation of our patent portfolio of $768,000, $636,000 and $285,000, respectively, for a increase of 21% for the 2014 period as compared to the same period in 2013, and an increase of 123% for the 2013 period as compared to the same period in 2012. We anticipate these expenses will decrease in 2015 compared to 2014. Increased costs in 2014 compared to 2013 were due to multiple international filings and activity on patent families related to IDO inhibitors.

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.

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 us). As a result of this transaction, BPS became a wholly-owned subsidiary of us 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 50,513 shares of our common stock.

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 SEC rules.

Recent Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The ASU eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders' equity. The amendments in the ASU will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. The Company early adopted this standard effective June 30, 2014. Adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

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 determined that our preferred stock outstanding prior to the IPO represented participating securities in accordance with ASC 260. For December 31, 2014, potentially dilutive stock options to purchase 979,048 shares of common stock had exercise prices that were greater than the average market price and restricted stock awards of 25,000 shares of common stock had market prices at their award dates that were greater than the average market price, were excluded from our calculation of diluted net income per share because to do so would be anti-dilutive. For December 31, 2013, and 2012, respectively, potentially dilutive common stock options of 4,486,564, and 3,752,413 were not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2014 and December 31, 2013, we had cash and cash equivalents and certificates of deposit of $202.8 million and $61.5 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 U.S. 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 expect to 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.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The report of KPMG LLP, our independent registered public accounting firm, the financial statements of us and our consolidated subsidiaries and the notes thereto are included beginning on page F-1.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures.

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of December 31, 2014. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2014, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) of the Exchange Act. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2014 based on criteria established in *Internal Control — Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. As a result of this assessment, management concluded that, as of December 31, 2014, our internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of our internal control over financial reporting as of December 31, 2014, was audited by our independent registered public accounting firm, KPMG LLP, as stated in its report, which is included in this filing on page F-1.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting during the fourth quarter of 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls.

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all internal control issues and instances of fraud, if any, have been detected.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item concerning our directors and nominees is incorporated by reference to our definitive Proxy Statement for our 2015 Annual Meeting of Stockholders, or the 2015 Proxy Statement.

Item 11. EXECUTIVE COMPENSATION

The information required by this item concerning the compensation of our directors and executive officers is incorporated by reference to the 2015 Proxy Statement.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item concerning securities authorized under our equity compensation plans and security ownership of certain beneficial owners is incorporated by reference to our 2015 Proxy Statement.

Securities Authorized For Issuance Under Equity Compensation Plans

We maintain our 2009 Equity Incentive Plan, 2010 Non-Employee Directors' Stock Award Plan and 2010 Employee Stock Purchase Plan, each of which was approved by the Company's security holders, pursuant to which we may grant equity awards to eligible persons.

The following table gives information about equity awards under the foregoing plans as of December 31, 2014:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	
Equity compensation plans approved by security holders	5,251,820	$9.79	1,133,902	(1)(2)
Equity compensation plans not approved by security holders	—	$0.00	—	
Total	5,251,820	$9.79	1,133,902	

(1) The 2009 Equity Incentive Plan incorporates an evergreen formula pursuant to which, on each January 1st, the aggregate number of shares reserved for issuance under the plan will increase by a number equal to 4% of the outstanding shares on December 31st of the preceding calendar year, or such lesser amount (or no shares) as determined by our Board.

(2) Of these shares, as of December 31, 2014, 654,935 shares remained available under the 2009 Equity Incentive Plan, 207,327 shares remained available under the 2010 Non-Employee Directors' Stock Award Plan and 271,640 shares remained available under the 2010 Employee Stock Purchase Plan.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item concerning transactions with related persons is incorporated by reference to our 2015 Proxy Statement.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item concerning fees and services of accountants and auditors is incorporated by reference to our 2015 Proxy Statement.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Item 15(a)

(1) Financial Statements

(2) Financial Statement Schedules

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto beginning on page F-1 of this report.

(3) Exhibits

The following exhibits are filed with this form 10-K or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3		Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1		Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2		Reference is made to Exhibits 3.1, 3.2 and 3.3				
4.3		Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.2	†	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers	S-1/A	11/8/2011	10.11	
10.3	†	2000 Equity Incentive Plan	S-1	12/21/2010	10.2	
10.4.1	†	Form of Stock Option Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.3	
10.4.2	†	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan	S-1	12/21/2010	10.4	
10.4.3	†	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.5	
10.5	†	Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.5.1	†	Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.5.2	†	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	
10.5.3	†	Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	
10.5.4	†	Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.7	

10.5.5	†	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8
10.6	†	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2
10.7	†	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.3
10.7.1	†	Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.4
10.7.2	†	Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.5
10.8	†	Employment Agreement, dated as of December 6, 2010, by and between the Registrant and Charles J. Link, Jr.	S-1	12/21/2010	10.12
10.9	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Nicholas N. Vahanian	S-1	12/21/2010	10.13
10.10	†	Employment Agreement, dated as of June 26, 2008, by and between the Registrant and Gordon H. Link, Jr.	S-1	12/21/2010	10.14
10.11	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Gordon H. Link, Jr.	S-1	12/21/2010	10.15
10.12	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Kenneth Lynn	S-1	12/21/2010	10.16
10.13	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and W. Jay Ramsey	S-1	12/21/2010	10.17
10.14	†	Form of Employee Proprietary Information and Inventions Agreement	S-1	12/21/2010	10.18
10.15	†	Promissory Note dated May 2, 2008 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.19
10.16	†	Promissory Note dated April 18, 2000 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.20
10.17	†	Promissory Note dated August 20, 2008 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.21
10.18	†	Promissory Note dated July 2008 by and between the Registrant and Gordon Link	S-1/A	2/28/2011	10.22
10.19	†	Amendment Agreement dated July 1, 2010 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.23
10.20	†	Amendment Agreement dated July 1, 2010 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.24
10.21	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.25
10.22	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.26
10.23	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Gordon Link	S-1/A	2/28/2011	10.27
10.24	†	Acknowledgment Agreement dated November 24, 2010 by and between BioProtection Systems Corporation and Charles Link	S-1/A	2/28/2011	10.28
10.25	†	Acknowledgment Agreement dated November 23, 2010 by and between BioProtection Systems Corporation and Nicholas Vahanian	S-1/A	2/28/2011	10.29
10.26	*	License Agreement dated July 7, 2005 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.30
10.26.1	*	First Amendment to License Agreement dated May 22, 2006 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.31
10.26.2	*	Second Amendment to License Agreement September 11, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.32
10.27	*	Exclusive License Agreement executed December 21, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.33
10.28	*	Exclusive License Agreement effective April 23, 2009 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.34
10.29	*	License Agreement dated October 13, 2004 by and between the Registrant and Drexel University	S-1/A	11/8/2011	10.36
10.30	*	License Agreement dated August 2, 2001 by and between the Registrant and Central Iowa Health System	S-1/A	11/8/2011	10.37
10.31	*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46

10.31.1	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47
10.31.2	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48
10.31.3	*	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49
10.31.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.31.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.32	*	Patent License Agreement dated March 1, 2006 by and between the Registrant and Bresagen Xenograft Marketing Ltd.	S-1/A	11/8/2011	10.50
10.33	*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation	S-1/A	11/8/2011	10.66
10.34	*	Sole License Agreement executed May 4, 2010 by and between Public Health Agency of Canada in Right of Canada and BioProtection Systems Corporation	S-1/A	11/8/2011	10.67
10.34.1		Amendment dated July 31, 2014 to the Sole License Agreement by and between BioProtection Systems Corporation and Public Health Agency of Canada in Right of Canada as Represented by the Minister of Health dated May 4, 2010	10-Q	11/10/2014	10.5
10.35	*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between the Registrant and National Cancer Institute	S-1/A	11/8/2011	10.38
10.35.1		Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.39
10.35.2		Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.40
10.35.3		Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.41
10.35.4		Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.42
10.35.5		Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.43
10.35.6		Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.44
10.35.7		Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.45
10.35.8		Amendment No. 8 to Letter of Intent for CRADA #2166 dated June 2, 2011 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.79
10.36		Lease dated September 1, 2000 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.46
10.37		Sublease Agreement effective February 1, 2001 by and between the Registrant and Iowa State Innovation System	S-1	12/21/2010	10.47
10.38		Memorandum of Agreement dated December 6, 2005 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.48
10.39		Memorandum of Agreement dated April 13, 2006 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.49
10.40		Memorandum of Agreement dated February 20, 2008 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.50
10.41		Memorandum of Agreement dated May 1, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.51
10.42		Memorandum of Agreement dated March 24, 2010 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.52

10.43		Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53
10.44		Lease dated August 10, 2005 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.82
10.45		Memorandum of Agreement dated September 29, 2011 by and between the Registrant and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.84
10.46		Memorandum of Agreement dated September 29, 2011 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.83
10.47		Memorandum of Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Iowa State University Research Park Corporation	8-K	11/18/2011	10.1
10.48		Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54
10.49		Forgivable Loan Agreement dated March 10, 2010 by and between the Registrant and City of Ames, Iowa	S-1	12/21/2010	10.55
10.50		Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.56
10.51		Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.52		Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59
10.53		Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.54		Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.55		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77
10.56		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.57		Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.68
10.57.1		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	S-1/A	2/28/2011	10.69
10.58	*	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	11/8/2011	10.70
10.58.1		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	S-1/A	10/4/2011	10.80
10.59		Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.71
10.59.1		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	S-1/A	2/28/2011	10.72
10.60		Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.73
10.61		Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.74
10.62		Grant Number 5R43AI084350-02 issued March 24, 2011 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	10/4/2011	10.81
10.63		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	S-1/A	2/28/2011	10.75
10.64		Certificate of Merger of BPS Merger Sub, Inc. into BioProtection Systems Corporation filed on January 7, 2011	S-1/A	2/28/2011	10.76

10.65		Standard Design-Build Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Story Construction Co.	8-K	11/18/2011	10.2
10.66		NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.67		NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.68		Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4
10.69		Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2013	8-K	3/28/2012	10.1
10.70	†	2012 Target Bonus Awards	8-K	3/28/2012	10.2
10.71	*	Cooperative Research and Development Agreement between the Company and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6
10.72		Letter of Resignation of Executive Vice President of Business Development, effective as of June 27, 2012	10-Q	8/14/2012	10.2
10.73	†	Offer of Employment for Head of Business Development, effective as of July 26, 2012	10-Q	8/14/2012	10.3
10.74	†	2013 Salaries and Target Bonus Awards	8-K	11/7/2012	10.1
10.75	†	2012 Named Executive Officer Bonus Awards	8-K	12/21/2012	10.1
10.76		Underwriting Agreement, effective as of January 30, 2013	8-K	1/31/2013	1.1
10.77		Memorandum of Agreement dated May 7, 2012 by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/15/2013	10.1
10.78		Memorandum of Agreement dated May 7, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.2
10.79		Memorandum of Agreement dated November 6, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.3
10.80	†	2013 Target Bonus Awards	8-K	4/5/2013	10.1
10.81		Memorandum of Agreement dated April 15, 2013 by and between the Registrant and Iowa State University Research Park Corporation	10-Q	5/8/2013	10.1
10.82		Story Construction Contract	10-Q	8/8/2013	10.1
10.83		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation Dated March 1, 2010	10-Q	8/8/2013	10.2
10.84	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Charles J. Link, Jr.	8-K	8/14/2013	10.1
10.85	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Nicholas N. Vahanian	8-K	8/14/2013	10.2
10.86	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Gordon H. Link, Jr.	8-K	8/14/2013	10.3
10.87	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and W. Jay Ramsey	8-K	8/14/2013	10.4
10.88		Controlled Equity OfferingSM Sales Agreement, dated September 5, 2013, by and between NewLink Genetics Corporation and Cantor Fitzgerald & Co.	8-K	9/5/2013	10.1
10.89		Amendment of Contract No. HDTRA1-09-C-0014, by and between BioProtection Systems Corporation and the United States Department of Defense, dated as of September 18, 2013	10-Q	11/12/2013	10.1
10.90		License Agreement Amendment, by and between NewLink Genetics Corporation and Georgia Health Sciences University Research Institute, dated as of July 13, 2013	10-Q	11/12/2013	10.2
10.91	†	2013 Bonus Awards	8-K	1/8/2014	10.1
10.92	†	2014 Salaries, Bonus Targets and Equity Awards	8-K	1/8/2014	10.2
10.93		Memorandum of Agreement, dated January 4, 2014, by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/12/2014	10.93
10.94	*	Amendment to License Agreement dated December 30, 2013, by and between Registrant and Central Iowa health System	10-K	3/12/2014	10.94

10.95	†	Employment Agreement, dated as of March 11, 2014, by and between the Registrant and Brian Wiley	10-K	3/12/2014	10.95	
10.96	†	Employment Agreement, dated as of March 11, 2014, by and between the Registrant and Carl W. Langren	10-K	3/12/2014	10.96	
10.97	*	Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.1	
10.98	*	Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L HyperAcute Pancreas by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.2	
10.99		Amendment dated September 30, 2014 to the Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec. Inc. dated June 19, 2014	10-Q	11/10/2014	10.2	
10.100		Separation and Release Agreement between the Company and Gordon H. Link, Jr., dated September 29, 2014	8-K	10/1/2014	10.1	
10.101		Offer Letter between the Company and Jack B. Henneman III, dated September 23, 2014	8-K	10/1/2014	10.2	
10.102	*	License and Collaboration Agreement dated October 16, 2014 by and among the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-LaRoche Ltd.	10-Q	11/10/2014	10.1	
10.103	†	2014 Bonus Awards	8-K	1/6/2015	10.1	
10.104	†	2015 Salaries, Bonus Targets and Equity Awards	8-K	1/6/2015	10.2	
10.105	*	License and Collaboration Agreement dated November 21, 2014 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.				X
10.106		Memorandum of Agreement dated October 25, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005				X
10.107		Memorandum of Agreement dated December 29, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010				X
10.108		Memorandum of Agreement dated February 12, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010				X
21.1		Subsidiary Information				X
23.1		Consent of KPMG LLP, independent registered public accounting firm				X
24.1		Power of Attorney (included on signature page hereto)				X
31.1		Rule 13a-14(a)/15d-14(a) Certification				X
31.2		Rule 13a-14(a)/15d-14(a) Certification				X
32.1	#	Section 1350 Certification				X
101.INS		XBRL Instance Document (filed electronically herewith)				
101.SCH		XBRL Taxonomy Extension Schema Document (filed electronically herewith)				
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document (filed electronically herewith)				
101.LAB		XBRL Taxonomy Extension Label Linkbase Document (filed electronically herewith)				
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document (filed electronically herewith)				
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document (filed electronically herewith)				

† 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 19434, as amended.

The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)
Date: March 16, 2015

By: /s/ John B. Henneman, III
John B. Henneman, III
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: March 16, 2015

By: /s/ Carl W. Langren
Carl W. Langren
Vice President Finance
(Principal Accounting Officer)
Date: March 16, 2015

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Charles J. Link, Jr. and John B. Henneman, III, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities indicated:

Name	Title	Date
/s/ Charles J. Link, Jr. Charles J. Link, Jr.	Chief Executive Officer, Chairman of Board of Directors and Director (Principal Executive Officer)	March 16, 2015
/s/ John B. Henneman, III John B. Henneman, III	Chief Financial Officer and Secretary (Principal Financial Officer)	March 16, 2015
/s/ Thomas A. Raffin Thomas A. Raffin	Director	March 16, 2015
/s/ Ernest J. Talarico, III Ernest J. Talarico, III	Director	March 16, 2015
/s/ Lota Zoth Lota Zoth	Director	March 16, 2015
/s/ Joseph Saluri Joseph Saluri	Director	March 16, 2015
/s/ Paul R. Edick Paul R. Edick	Director	March 16, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
NewLink Genetics Corporation:

We have audited the accompanying consolidated balance sheets of NewLink Genetics Corporation and subsidiaries (the Company) as of December 31, 2014 and 2013, and the related consolidated statements of operations, equity, and cash flows for each of the years in the three-year period ended December 31, 2014. We also have audited the Company's internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Report on Internal Control over Financial Reporting* included in Item 9A. Our responsibility is to express an opinion on these consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the consolidated financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of NewLink Genetics Corporation and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles. Also in our opinion, NewLink Genetics Corporation and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control - Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

/s/ KPMG LLP

Des Moines, Iowa
March 16, 2015

NewLink Genetics Corporation
and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 190,404	$ 61,291
Certificates of deposit	12,393	249
Prepaid expenses	8,333	773
State research and development credit receivable	13	329
Income tax receivable	15,604	—
Other receivables	3,716	1,328
Total current assets	230,463	63,970
Leasehold improvements and equipment:		
Leasehold improvements	6,022	5,588
Computer equipment	1,399	1,133
Lab equipment	4,110	3,724
Contract manufacturing organization equipment	1,023	—
Total leasehold improvements and equipment	12,554	10,445
Less accumulated depreciation and amortization	(4,955)	(3,858)
Leasehold improvements and equipment, net	7,599	6,587
Total assets	$ 238,062	$ 70,557

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and per share data)

	December 31, 2014	December 31, 2013
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,412	$ 612
Accrued expenses	9,367	2,861
Income taxes payable	—	130
Current portion of unearned revenue	12,966	—
Current portion of deferred rent	84	84
Current portion of obligations under capital leases	35	35
Current portion of notes payable	157	154
Total current liabilities	25,021	3,876
Long term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	941	1,033
Unearned revenue	1,085	—
Deferred rent	1,238	1,321
Total long-term liabilities	9,264	8,354
Total liabilities	34,285	12,230
Stockholders' Equity		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at December 31, 2014 and 2013; issued and outstanding shares — 0 at December 31, 2014 and 2013	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at December 31, 2014 and 2013; issued 27,991,242 and 26,573,023 at December 31, 2014 and 2013 and outstanding 27,980,849 and 26,573,023 at December 31, 2014 and December 31, 2013	280	266
Additional paid-in capital	236,838	194,038
Treasury stock, at cost: 10,393 shares at December 31, 2014	(222)	—
Accumulated deficit	(33,119)	(135,977)
Total stockholders' equity	203,777	58,327
Total liabilities and stockholders' equity	$ 238,062	$ 70,557

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended December 31,		
	2014	2013	2012
Grant revenue	$ 6,642	$ 1,093	$ 1,687
Licensing revenue	165,950	—	—
Total operating revenues	172,592	1,093	1,687
Operating expenses:			
Research and development	35,691	22,713	17,838
General and administrative	19,328	9,521	7,108
Total operating expenses	55,019	32,234	24,946
Income (loss) from operations	117,573	(31,141)	(23,259)
Other income and expense:			
Miscellaneous income (expense)	—	112	(38)
Interest income	86	12	14
Interest expense	(26)	(33)	(38)
Other income (expense), net	60	91	(62)
Net income (loss) before taxes	117,633	(31,050)	(23,321)
Income tax expense	(14,775)	(130)	—
Net income (loss)	$ 102,858	$ (31,180)	$ (23,321)
Basic earnings (loss) per share	$ 3.69	$ (1.23)	$ (1.12)
Diluted earnings (loss) per share	$ 3.32	$ (1.23)	$ (1.12)
Basic average shares outstanding	27,838,873	25,275,179	20,779,450
Diluted average shares outstanding	31,025,099	25,275,179	20,779,450

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Equity
(In thousands, except share and per share data)

	Common Stock					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2011	20,591,240	$ 206	$ 118,043	$ —	$ (81,476)	$ 36,773
Share-based compensation	13,000	—	3,195	—	—	3,195
Exercise of stock options	341,429	4	883	—	—	887
Sale of shares under stock purchase plan	39,523	—	239	—	—	239
Purchase of fractional shares	—	—	(4)	—	—	(4)
Reduction of IPO offering costs	—	—	158	—	—	158
Net loss	—	—	—	—	(23,321)	(23,321)
Balance at December 31, 2012	20,985,192	210	122,514	—	(104,797)	17,927
Share-based compensation	—	—	4,365	—	—	4,365
Exercise of stock options	107,541	1	441	—	—	442
Sale of shares under stock purchase plan	63,669	1	415	—	—	416
Issuance of 4,600,000 shares of common stock (net of offering costs of $3,524,405) (February 4, 2013)	4,600,000	46	48,870	—	—	48,916
Issuance of shares under at the market offering (net of offering costs of $402,542)	816,621	8	17,433	—	—	17,441
Net loss	—	—	—	—	(31,180)	(31,180)
Balance at December 31, 2013	26,573,023	266	194,038	—	(135,977)	58,327
Share-based compensation	—	—	8,613	—	—	8,613
Exercise of stock options and restricted stock awards	375,834	4	1,857	—	—	1,861
Sales of shares under stock purchase plan	25,168	—	466	—	—	466
Issuance of common stock under the ATM Offering(net of offering costs of $692, January and February 2014)	1,017,217	10	27,562	—	—	27,572
Shares withheld for statutory tax withholding (September 30, 2014)	(10,393)	—	—	(222)	—	(222)
Excess tax benefits from share-based compensation awards	—	—	4,302	—	—	4,302
Net income	—	—	—	—	102,858	102,858
Balance at December 31, 2014	27,980,849	$ 280	$ 236,838	$ (222)	$ (33,119)	$ 203,777

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Cash Flows From Operating Activities			
Net income (loss)	$ 102,858	$ (31,180)	$ (23,321)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Share-based compensation	8,613	4,365	3,195
Depreciation and amortization	1,097	891	788
Loss on sale of fixed assets	—	2	38
Changes in operating assets and liabilities:			
Prepaid expenses	(7,560)	134	(498)
State research and development credit receivable	316	213	(340)
Other receivables	(2,388)	(1,132)	—
Accounts payable and accrued expenses	7,898	843	(909)
Income taxes (receivable) payable	(15,734)	130	—
Unearned revenue	14,051	—	—
Deferred rent	(83)	(84)	576
Net cash provided by (used in) operating activities	109,068	(25,818)	(20,471)
Cash Flows From Investing Activities			
Purchase of certificates of deposit	(17,377)	(249)	(1,992)
Maturity of certificates of deposit	5,233	1,494	2,988
Purchase of equipment	(1,700)	(1,386)	(1,323)
Proceeds on sale of equipment	—	—	50
Net cash used in investing activities	(13,844)	(141)	(277)
Cash Flows From Financing Activities			
Issuance of common stock, net of offering costs	27,572	66,357	158
Issuance of common stock under share-based compensation plans	2,327	858	1,127
Excess tax benefits from share-based compensation awards	4,302	—	—
Repurchase of common stock	(222)	—	(4)
Proceeds from notes payable	97	—	456
Principal payments on notes payable	(154)	(149)	(107)
Payments under capital lease obligations	(33)	(66)	(122)
Net cash provided by financing activities	33,889	67,000	1,508
Net increase (decrease) in cash and cash equivalents	129,113	41,041	(19,240)
Cash and cash equivalents at beginning of year	61,291	20,250	39,490
Cash and cash equivalents at end of year	$ 190,404	$ 61,291	$ 20,250
Supplemental disclosure of cash flows information:			
Cash paid for interest	$ 26	$ 34	$ 38
Cash paid for taxes	26,443	—	—
Noncash financing and investing activities:			
Purchased leasehold improvements and equipment in accounts payable and accrued expenses	409	—	53
Assets acquired under capital lease	—	54	—
Reduction of IPO offering costs	—	—	158

See accompanying notes to consolidated financial statements.

NewLink Genetics Corporation
and Subsidiaries
Notes to Consolidated Financial Statements

1. Description of Business 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.

In 2005, NewLink created a partially 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. 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 owning all the outstanding capital stock of BPS.

In 2013, NewLink created a wholly owned subsidiary, NewLink International (NI). NewLink plans to conduct all or a portion of its operations outside of the United States through NI. During 2014, NewLink created another wholly-owned subsidiary, NewLink Global (NG), which was subsequently merged into NewLink during 2014.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs. The Company earned net income of $102.9 million for the year ended December 31, 2014, primarily as a result of entering into two license and collaboration agreements during 2014. See Note 5. The Company has managed its liquidity needs historically through a series of capital market transactions. On February 4, 2013, the Company completed an offering of common stock. The Company sold 4,600,000 shares of common stock at a price of $11.40 per share raising a total of $49.0 million in net proceeds.

NewLink entered into a sales agreement with Cantor Fitzgerald & Co., dated as of September 5, 2013, under which NewLink may sell up to $60.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the ATM Offering). Any such sales would be effected pursuant to its registration statement on Form S-3 (333-185721), declared effective by the SEC on January 4, 2013. As of December 31, 2014, the Company had sold 1,833,838 shares of common stock under the ATM Offering, raising a total of $45.2 million in net proceeds. Subsequent to December 31, 2014 and through March 4, 2015, the Company sold an additional 329,402 shares of common stock under the ATM Offering, raising an additional $13.6 million in net proceeds.

The accompanying financial statements as of and for the year ended December 31, 2014 have been prepared assuming the Company will continue as a going concern. The Company successfully raised net proceeds of $37.6 million from its IPO, completed a follow-on offering of its common stock raising net proceeds of $49.0 million, raised an additional $45.2 million in net proceeds from the ATM Offering prior to December 31, 2014 and raised an additional $13.6 million in net proceeds from the ATM Offering subsequent to December 31, 2014 and through March 4, 2015. The Company earned net income of $102.9 million and generated $109.1 million of operating cash flows for the year ended December 31, 2014, primarily as a result of entering into two license and collaboration agreements during 2014. The Company's cash and cash equivalents after these agreements and offerings are expected to be adequate to satisfy the Company's liquidity requirements well into 2016, although not through commercialization and launch of revenue producing products. If available liquidity becomes insufficient to meet the Company’s operating obligations as they come due, the Company'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 may have a material adverse effect on its business and financial position, and may materially affect the Company’s ability to continue as a going concern.

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 wholly-owned subsidiaries. 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 and cash equivalents of $190.4 million and $61.3 million at December 31, 2014 and 2013, respectively, consist of checking accounts, money market accounts and treasury bills.

(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 2016 and are presented at amortized cost, which approximates fair value.

(e) Leasehold Improvements and Equipment, and Deferred Rent

Leasehold improvements and equipment are capitalized as we believe they have alternative future uses and are stated at cost. Equipment under capital leases is stated at the present value of minimum lease payments. 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, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Deferred rent reflects improvement allowances from the Company's lessors deferred to be recognized as part of lease expense over the remaining term of the lease, which is recognized on a straight-line basis. During 2012, 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 $622,000 for improvements made to the facility. Total deferred rents were $1.3 million and $1.4 million as of December 31, 2014, and 2013, respectively.

(f) 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 at 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.

(g) Revenue Recognition

The Company recognizes revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or as services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

The Company follows ASC 605-25, Revenue Recognition - Multiple-Element Arrangements and ASC 808, Collaborative Arrangements , if applicable, to determine the recognition of revenue under our license and collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) clinical supply, and/or (iv) participation on joint research or joint steering committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Company typically receives non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. If management believes that the license to our intellectual property has stand-alone value, the Company generally recognizes revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, the Company would recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. When the performance period is not specifically identifiable from the agreement, the Company would estimate the performance period based upon provisions contained within the agreement, such as the duration of the research or development term.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Company recognizes a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of collaborator's performance are recognized when earned.

The Company earned net income of $102.9 million for the year ended December 31, 2014, primarily as a result of entering into two license and collaboration agreements during 2014.

The Company receives payments from government entities under its grants and contracts with the National Institute of Health, the Department of Defense, and the United States Department of Health and Human Services. These agreements provide the Company cost reimbursement for certain types of expenditures in return for research and development activities over a contractually defined period. Grant 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 the Company has only perfunctory obligations outstanding. During the years ended December 31, 2014, 2013, and 2012 , the Company has earned $6.6 million, $1.1 million, and $1.7 million in grant revenue, respectively.

(h) 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 organizations that conduct and manage clinical trials on behalf of the Company. Invoicing from third-party contractors for services performed can lag several months. The Company accrues the costs of services rendered in connection with third-party contractor activities based on its estimate of management fees, site management and monitoring costs and data management costs as contracted. Differences between actual clinical trial costs and estimated clinical trial costs and are adjusted for in the period in which they become known through operations.

(i) 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 $748,000 at December 31, 2014 are reflected as a reduction in income taxes on the accompanying consolidated statements of operations. State research and development credits of $329,000, and $283,000 at December 31, 2013 and 2012, respectively, are reflected as a reduction of research and development expenses on the accompanying consolidated statements of operations.

(j) Patents

The Company generally applies for patent protection on processes and products. Patent application costs are expensed as incurred as a component of general and administrative expense, as recoverability of such expenditures is uncertain.

(k) 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. Management assesses the realizability of deferred tax assets and records a valuation allowance if it is more likely than not that all or a portion of the deferred tax assets will not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. As of December 31, 2014 and 2013, the Company has not recognized any uncertain tax positions.

(l) Share-Based Compensation

The Company is required to estimate the grant-date fair value of share-based compensation options issued to employees and recognize this cost over the period these awards vest. For purposes of estimating the grant-date fair value, the date of grant is the effective date on which the Board of Directors or the Chief Executive Officer, as applicable, grants the award, and the employee has a mutual understanding of the terms of the award. The service inception date is typically the date of grant. The Company estimates the fair value of each option granted using the Black-Scholes option pricing model. In addition, the Company has granted restricted stock units the fair value of which is based on the Company's stock price on the date of the grant. 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 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 granted prior to the IPO were granted with an exercise price as determined by the NewLink Board of Directors in good faith with the assistance of a third-party appraisal report and an evaluation of milestones achieved. Subsequent to the IPO, the Company uses the quoted market price as listed on the public exchange on the date of grant. If Incentive Stock Options (ISO) are granted to a 10% stockholder in the Company, the exercise price shall not be less than 110% of the common stock’s fair market value on the date of grant.

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 uses historical exercise and option expiration data to estimate the expected term for the Black-Scholes grant-date valuation.

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.

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

The Company estimates future expected volatility for each stock option valuation using a weighting of the Company's stock volatility and 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.

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.

(m) Segments

The Company operates in one segment. NewLink and its subsidiaries BPS and NI 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 the biopharmaceutical industry. The chief operating decision maker uses cash flow as the primary measure to manage the business and management does not segment its business for internal reporting or decision-making.

(n) Financial Instruments and Concentrations of Credit Risk

The fair values of cash and cash equivalents, certificates of deposit, receivables and accounts payable, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. The fair value of notes payable and capital lease obligations was $1.1 million and $1.2 million as of December 31, 2014 and 2013, respectively, and was determined using Level 3 inputs. The Company is unable to estimate the fair value of the royalty obligation based on future product sales as the timing of payments, if any, is uncertain.

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.

(o) Earnings per share (EPS)

We compute basic EPS attributable to the Company's common stockholders by dividing net income (loss) attributable to the Company by our weighted-average common shares outstanding, during the period. Diluted EPS reflects the potential dilution beyond shares for basic EPS that could occur if securities or other contracts to issue common stock were exercised, converted into common stock, or resulted in the issuance of common stock that would have shared in our earnings. We compute basic and diluted EPS using net income (loss) attributable to the Company's common stockholders, and our actual weighted-average shares.

(p) Concentration of Revenue

Prior to 2014, the Company's revenue was primarily obtained from government research grants. Genentech, a member of the Roche Group, ("Genentech") and Merck Sharpe & Dohme Corp. ("Merck") accounted for 78.9% and 17.2%, respectively, of the $172.6 million of revenue earned for the year ending December 31, 2014, with the remainder obtained from government grants.

(q) Recent Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. The ASU eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders' equity. The amendments in the ASU will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. The Company

early adopted this standard effective June 30, 2014. Adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

3. 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,	
Class of property	**2014**	**2013**
Lab equipment	$ 489	$ 489
Leasehold improvements	27	27
Computer equipment	54	54
Total property under capital leases	570	570
Less accumulated depreciation and amortization	384	293
Capital leased assets, net	$ 186	$ 277

The depreciation and amortization reflected above has been recorded in both research and development and general administrative expense in the consolidated statements of operations.

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, 2014 (in thousands):

Year ending December 31:	
2015	$ 36
2016	12
Total minimum lease payments	48
Less amount representing interest	1
Present value of net minimum lease payments	$ 47

(b) Operating Leases

The Company has certain facility leases with terms ranging between one and five years. Lease expense is recognized on a straight-line basis. Rental expense for operating leases during the years ended December 31, 2014, 2013 and 2012, was $1.2 million, $766,000, and $707,000 respectively, including those with terms less than one year, and has been included in both research and development and general and administration in the consolidated statement of operations. In February 2015, the Company entered into an amendment to a facilities operating lease extending the term through 2020.

Future minimum lease payments under the noncancelable operating leases (with initial or remaining lease terms in excess of one year) as of December 31, 2014 are as follows (in thousands):

Year ending December 31:		
2015	$	1,187
2016		1,136
2017		788
2018		430
2019		387
Thereafter		32
Total	$	3,960

4. Long-Term Debt and Conversion to Royalty Obligation

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 (the IDED). Under the agreement, in the absence of default, there were no principal or interest payments due until the completion date for the project. The balance outstanding under the loan agreement was $6.0 million as of December 31, 2011. This loan was converted into a royalty obligation under the terms of a settlement agreement entered into on March 26, 2012, (the IEDA Agreement) with the Iowa Economic Development Authority (the IEDA), as successor in interest to the IDED.

March 2012 IEDA Royalty Obligation

Under the terms of the IEDA Agreement the Company agreed to pay a 0.5% royalty on future product sales up to a cap of $6.8 million in exchange for IDED’s release of the Company's job creation and project expenditure obligations and their release of the security interest in substantially all of the Company's assets. As no payments are expected in the next 12 months, the entire accrued royalty obligation of $6.0 million is considered long-term as of December 31, 2014.

2009 and 2012 Iowa State University Research Park Notes

In 2009, the Company executed a promissory note in favor of Iowa State University Research Park (ISURP) in an original principal amount of $800,000, which is due in monthly installments through March, 2018. 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. The balance outstanding under the 2009 note was $348,000 and $449,000 at December 31, 2014 and December 31, 2013, respectively.

In 2012, the Company executed a promissory note in favor of ISURP in an original principal amount of $456,000, which is due in monthly installments through September 2020. The note represents amounts owed by the Company to ISURP for certain additional 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. The balance outstanding under the 2012 note was $339,000 and $392,000 at December 31, 2014 and December 31, 2013, respectively.

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 was March 10, 2015. In March 2015, the City of Ames granted a one year extension to obtain the required number of jobs.

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, 2016, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2016, the Company has failed to create or retain at least 150 full-time jobs in Ames, Iowa, the Company will be required to repay approximately $3,100 per job not created or retained following such date. As of December 31, 2014, $397,000 of the total $400,000 forgivable loan was advanced to the Company. 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.

5. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into a worldwide exclusive collaboration and license agreements with Genentech for the development and commercialization of NLG919, one of NewLink's clinical stage IDO pathway inhibitors. The parties also entered into a research collaboration for the discovery of next generation IDO/TDO compounds to be developed and commercialized under this agreement. Under the terms of the agreement, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech and is eligible to receive additional payments of over $1.0 billion upon achieving certain NLG919 and Next Generation Product Development regulatory development, international patent acceptance, country marketing approval, and sales-based milestones. The Company is also eligible to receive escalating double digit royalty payments on potential commercial sales of multiple products by Genentech.

The Company is obligated to deliver multiple non-contingent deliverables related to the NLG919 upfront cash payment. These deliverables include the NLG919 development and commercialization license, research license, program materials and technology, clinical supply of NLG919 product, manufacturing technology, participation in a joint research committee (JRC), and providing an alliance manager. The NLG919 development and commercialization license and research license are separate deliverables, but without the ability to develop NLG919, the ability to perform research on the compound would not benefit Genentech. Therefore, the Company believes that the value of the development and commercialization license cannot be separated from the research license value and the two are valued together. The other deliverables qualify as separate units of accounting.

The respective standalone value from each of these deliverables has been determined by applying the best estimated selling price method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of service. The estimated selling price determination required the use of significant estimates. To determine the stand-alone value of the license, we considered the negotiation discussions that led to the final terms of the agreement. The Company utilized historical cost plus an estimated gross margin to estimate the selling price for program materials and technology, manufacturing technology, clinical supply, participation in a JRC, and participation of an alliance manager. The program materials and technology, clinical supply of NLG919, participation in a JRC and participation of an alliance manager are expected to be delivered throughout the duration of the agreement. The license and manufacturing technology was delivered shortly after the effective date of the agreement.

For the year ended December 31, 2014 the Company recognized revenue under this agreement of $136.2 million associated with license and manufacturing technology transfer deliverables, which were completed in their entirety. In accordance with the Company’s continuing performance obligation, $13.8 million of the $150.0 million upfront payment is being deferred and recognized in future years. The agreement up-front payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

The Company will apply the contingency-adjusted performance model to recognize revenue related to potential future milestones under the agreement, therefore, revenue will only be recognized upon the achievement of a milestone.

The Company is eligible to receive from Genentech tiered royalty payments based on product sales, with royalty rates varying based on the territory of the sales, the product, the licenses incorporated in the development, and the opt-in by NewLink during development. Royalties will be accounted for as contingent revenue and will be recognized as earned in accordance with contract terms, when Genentech results are reported, the amount can be reasonably estimated, and collectability is reasonably assured.

Merck Sharpe & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement with Merck to develop, manufacture and commercialize rVSV-EBOV, an Ebola vaccine the Company licensed from the Public Health Agency of Canada, or PHAC. Under the terms of the agreement, the Company granted Merck an exclusive, royalty-bearing license to the rVSV-EBOV and related technology. Accordingly, the accounting for the transaction commences in the fourth quarter of 2014. NewLink received a $30.0 million non-refundable, upfront payment in December 2014, and was also eligible for a one-time $20.0 million non-refundable milestone payment upon the initiation of the pivotal clinical trial using the current rVSV-EBOV vaccine product as one arm of the trial. In February 2015, this milestone was achieved and the Company received the milestone payment. In addition, NewLink can receive escalating royalties on potential commercial sales by Merck of the current product candidate ranging from single digit to double digits on the rVSV-EBOV license agreement product sales and escalating royalties on potential commercial sales by Merck of products other than current products within the Company's patent rights ranging from low to high single digit, on increasing levels of annual net sales worldwide. Merck will lead the development of rVSV-EBOV and any other rVSV-based viral hemorrhagic fever (VHF) vaccine product candidates in order to create a marketable product safe for human use.

The Company is obligated to deliver multiple non-contingent deliverables related to the rVSV-EBOV upfront cash payment. These deliverables include the license, information and know-how, technology transfer, participation in a joint steering committee ("JSC"), and providing a project leader. These deliverables qualify as separate units of accounting. The respective standalone value from each of these deliverables has been determined by applying the best estimated selling price method and the revenue allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of service. The determination of the best estimated selling price required the use of significant estimates. To determine the stand alone value of the license, we considered the negotiation discussions that led to the final terms of the agreement. The Company used historical cost plus an estimated gross margin to estimate the selling price for information and know-how, technology transfer, participation in the JSC, and providing a project leader. The technology transfer, participation in the JSC and providing a project leader are expected to be delivered throughout the duration of the agreement. The license and information and know-how was delivered shortly after the effective date of the agreement.

For the year ended December 31, 2014 the Company recognized revenue under this agreement of $29.6 million associated with license and information and know-how, which were completed in their entirety, and an additional $170,000 associated with the remaining deliverables. In accordance with the Company's continuing performance obligations, $232,000 of the $30.0 million upfront payment is being deferred and recognized in future years. The agreement up-front payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

The Company will apply the contingency-adjusted performance model to recognize revenue related to potential future milestones under the agreement, therefore, revenue was recognized in the first quarter of 2015 upon the achievement of the milestone.

The Company is eligible to receive from Merck tiered royalty payments based on product sales, with royalty rates varying based on Merck sales of the current rVSV-EBOV vaccine product and Merck sales of other products included within the Company's patent rights. Royalties will be recognized as earned in accordance with contract terms, when Merck results are reported, the amount can be reasonably estimated, and collectability is reasonably assured.

6. 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.

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.

7. Preferred Stock

As of December 31, 2014 and 2013, the Company had no outstanding preferred stock. The NewLink Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the voting power and such designations, preferences, and rights of such series, subject to approval of outstanding preferred series shareholders.

8. Common Stock Equity Incentive Plans

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, members of the NewLink Board of Directors, advisors, and consultants to NewLink. As of December 31, 2014 there were 6,799,854 shares of common stock authorized for the 2009 Plan and 654,935 shares remained available for issuance. As of December 31, 2013 there were 5,733,514 shares of common stock authorized for the 2009 plan and 671,348 shares remained available for issuance.

On January 7, 2011, stockholders authorized an increase of 714,286 shares of common stock available for issuance under the 2009 Plan. On January 1, 2013 an additional 838,375 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2014, an additional 1,066,340 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. Subsequent to year end, on January 1, 2015 an additional 1,119,255 shares of commons stock were added to the shares reserved for future issuance under the 2009 Plan. The shares added to the reserve on January 1, 2013, January 1, 2014, and January 1, 2015 were added pursuant to an "evergreen provision", in accordance with which, on January 1 of each year, from 2012 to (and including) 2019, a number of shares of Common Stock in an amount equal to 4% of the total number of shares of Common Stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the NewLink Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Option Plan (the Directors' Plan), which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the reserve. As of December 31, 2014, 207,327 shares remained available for issuance under the Directors' Plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan, (the 2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the reserve. As of December 31, 2014, 271,640 shares remained available for issuance under the plan. During the years ending December 31, 2014 and 2013, 25,168 and 63,669 shares of common stock, respectively, were purchased under the terms of the 2010 Purchase Plan.

Share-based Compensation

Share-based employee compensation expense for the years ended December 31, 2014, 2013 and 2012, was $8.6 million, $4.4 million, $3.2 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations. As of December 31, 2014, the total compensation cost related to nonvested option awards not yet recognized was $18.8 million and the weighted average period over which it is expected to be recognized was 3 years. The total income tax benefit recognized in the consolidated statements of income for stock-based compensation arrangements was $3.7 million, $0 and $0 for the years ended December 31, 2014, 2013 and 2012, respectively.

Stock Options

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 was 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.

The following table summarizes the stock option activity for the year ended December 31, 2014:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	4,486,564	$ 5.89	
Options granted	974,555	24.38	
Options exercised	(330,134)	5.64	
Options forfeited	(32,674)	16.53	
Options expired	—	—	
Outstanding at end of period	5,098,311	$ 9.38	6.3
Options exercisable at end of period	3,678,956	$ 5.50	5.3

Based on the December 31, 2014 price of $39.75 per share, the intrinsic value of stock options outstanding at December 31, 2014, was $154.9 million, of which $126.0 million and $28.9 million related to stock options that were vested and unvested, respectively, at that date.

The following table summarizes options that were granted during the years ended December 31, 2014, 2013 and 2012, and the range of assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

	Years Ended December 31,		
	2014	2013	2012
Number of options granted	974,555	860,250	672,079
Risk-free interest rate	1.73%-2.24%	.89%-2.14%	.98%-2.05%
Expected dividend yield	—	—	—
Expected volatility	57.4%-68.3%	61.4%-67.3%	63.05%-73.6%
Expected term (in years)	6.0-7.0	4.8-7.0	5.8-7.0
Weighted average grant-date fair value per share	$14.80	$7.50	$5.02

The following table summarizes the intrinsic value of options exercised and the fair value of awards vested during the years ended December 31, 2014, 2013 and 2012:

	Years Ended December 31,		
	2014	2013	2012
Intrinsic value of options exercised	$8.5 million	$1.6 million	$3.6 million
Fair value of awards vested	$7.5 million	$3.0 million	$2.5 million

The fair value of options vested for the year ended December 31, 2014, includes $1.7 million in share-based compensation resulting from the vesting in full of one employee's options upon the employee's termination that occurred during 2014.

Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for so long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and

to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are equity classified within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's Common Stock on the NASDAQ Stock Market on the date of grant.

During the year ended December 31, 2014 and 2013, there were 204,209 and 0 shares of restricted stock granted, respectively. These restricted stock grants had a weighted average fair value (per share) at date of grant of $23.16. At December 31, 2014 and 2013, there were 153,509 and 0 shares of unvested restricted stock outstanding, respectively. Compensation expense is determined for the issuance of restricted stock by amortizing over the requisite service period, or the vesting period, the aggregate fair value of the restricted stock awarded based on the closing price of the Company's common stock on the date of grant.

A summary of the Company's unvested restricted stock at December 31, 2014 and changes during the year ended December 31, 2014 is as follows:

	Restricted Stock	Weighted Average Grant Date Fair Value
Unvested at beginning of period	—	$ —
Granted	204,209	23.16
Vested	(45,700)	21.38
Forfeited/cancelled	(5,000)	24.88
Unvested restricted stock at end of period	153,509	$ 23.63

As of December 31, 2014, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $3.0 million and is expected to be recognized over a weighted-average period of 3.4 years. The grant date fair value of awards granted during the year ended December 31, 2014 was $4.7 million. The fair value of awards vested during the year ended December 31, 2014 was $1.0 million.

NewLink does not have a formal policy regarding the source of shares issued upon exercise of stock options or issuance of restricted stock. NewLink expects shares issued to be issued from treasury shares or new shares.

On January 2, 2015, NewLink approved grants of restricted stock unit awards to certain of the named executive officers for extraordinary performance in 2014. These are recognized as 2015 grants.

9. Income Taxes

Income tax expense consists of (in thousands):

	Current	Deferred	Total
Year Ended December 31, 2014:			
U.S. federal	$ 8,503	$ —	$ 8,503
State and local	6,272	—	6,272
	$ 14,775	$ —	$ 14,775
Year Ended December 31, 2013:			
U.S. federal	$ 130	$ —	$ 130
State and local	—	—	—
	$ 130	$ —	$ 130
Year Ended December 31, 2012:			
U.S. federal	$ —	$ —	$ —
State and local	—	—	—
	$ —	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of deferred tax assets and the deferred tax liability at December 31, 2014 and 2013 are presented below (in thousands):

	Year Ended December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$ 966	$ 18,556
Federal research and development tax credits	120	4,322
Share-based compensation	5,191	1,748
Deferred rent	550	295
Minimum tax credits	—	120
Accrued compensation	252	107
Accrued expenses	62	—
Leasehold improvements and equipment	—	20
Gross deferred tax assets	7,141	25,168
Less valuation allowance	(7,114)	(25,168)
Net deferred tax assets	27	—
Deferred tax liability:		
Leasehold improvements and equipment	(27)	—
Total net deferred tax assets	$ —	$ —

The valuation allowance for deferred tax assets as of December 31, 2014 and 2013 was $7.1 million and $25.2 million, respectively. The net change in the total valuation allowance for the years ended December 31, 2014 and 2013 was a decrease of $18.1 million and increase of $2.0 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, 2014 and 2013, due to the uncertainty of future recoverability.

Federal operating loss carryforwards as of December 31, 2014 of approximately $2.3 million and federal research credit carryforwards of approximately $120,000 expire at various dates from 2026 through 2031. 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 analysis from its inception through December 31, 2014, NewLink experienced Section 382 ownership changes in September 2001 and March 2003 and BPS experienced Section 382 ownership changes in January 2006 and January 2011 and the reported deferred tax assets reflect these expected limitations. These ownership changes limited NewLink's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of NewLink and our subsidiary. 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.

Income tax expense was $14.8 million, $130,000, and $0 for the years ended December 31, 2014, 2013 and 2012.

A reconciliation of income taxes at the statutory federal income tax rate to net income taxes included in the accompanying statements of operations is set forth in the following table:

	Year ended December 31,		
	2014	2013	2012
U.S. federal income tax expense at the statutory rate	35.0 %	35.0 %	35.0 %
Available research and experimentation tax credits	(12.8)	—	—
State income taxes, net of federal taxes	4.7	—	—
Loss in foreign subsidiary	8.4	—	—
Valuation allowance	(21.6)	(38.3)	(35.0)
Other	(1.1)	2.9	—
Total	12.6 %	(0.4)%	— %

The loss in foreign subsidiary reconciling item in the above table is the tax effect of intercompany research and development expenses which are not deductible on the Company's consolidated federal income tax return.

10. Earning Per Share (EPS)

The following table presents the calculations of earnings (loss) per share:

	Years Ended December 31,		
	2014	2013	2012
Historical net income (loss) per share			
Numerator			
Net income (loss) attributable to common stockholders	$ 102,858	$ (31,180)	$ (23,321)
Denominator			
Basic weighted-average shares outstanding	27,838,873	25,275,179	20,779,450
Dilutive effect of stock option and restricted stock shares	3,186,226	—	—
Diluted weighted-average shares outstanding	31,025,099	25,275,179	20,779,450
Basic earnings (loss) per share	$ 3.69	$ (1.23)	$ (1.12)
Diluted earnings (loss) per share	$ 3.32	$ (1.23)	$ (1.12)

For December 31, 2014, potentially dilutive stock options to purchase 979,048 shares of common stock had exercise prices that were greater than the average market price and restricted stock awards of 25,000 shares of common stock had market prices at their award dates that were greater than the average market price, were excluded from our calculation of diluted net income per share because to do so would be anti-dilutive. For December 31, 2013, and 2012, respectively, potentially dilutive common stock options of 4,486,564, and 3,752,413 were not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive.

11. Licensing Agreements

The Company is a party to a number of licensing agreements with respect to certain of the technologies that underlie its intellectual property. 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 recognizes expense under its licensing agreements in the period the obligation is incurred. These agreements typically provide for a license fee based on a percent of sales and annual minimum royalties. For additional information regarding how the Company records payments under these agreements, see note 2(i) above. The Company has incurred expense of approximately $3.1 million, $88,000, and $255,000, under all of the in-licensing agreements for the years ended December 31, 2014, 2013, and 2012, respectively, which is recorded as a component of general and administrative expenses.

Under certain license agreements the Company is obligated to make potential milestone payments as listed in the following table. In addition to the milestone payments, each license is paid as a low single digit percentage of net sales of the licensed product, subject to annual minimum royalties. These obligations are contingent upon achieving the applicable milestone event, the timing of which cannot presently be determined. The milestone payments and royalty payments are in place through at least the expiration of certain of the Company's patents, which is currently 2029 and beyond.

Licensor	Aggregate potential milestone payments
Drexel University	$1 million per licensed product
Lankenau Institute for Medical Research under the IDO-1 Agreement	$1.36 million per licensed product
Lankenau Institute for Medical Research under the LIMR IDO-2 Agreement	$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	$610,000 per licensed product, subject to reductions if milestones also qualify under the IDO-1 Agreement or LIMR IDO-2 Agreement
Georgia Regents Research Institute	$2.8 million per licensed product
Public Health Agency of Canada	C$205,000 per licensed product
The Ohio State University	$2.75 million for first licensed product

12. Employee Benefit Plans

The Company sponsors a 401(k) plan, which includes a defined contribution feature. The Company's defined contribution was $303,000, $198,000, $136,000 for the years ended December 31, 2014, 2013 and 2012, respectively. The Company made discretionary contributions to the plan of $299,000, $144,000, and $152,000 for the years ended December 31, 2014, 2013 and 2012, respectively.

The Company has approved employment agreements for certain executives, dated October 29, 2010, as amended August 13, 2013, that provide for the payment of 6 to 24 months of base salary, bonus, and group health insurance premiums plus accrued obligations upon termination of the executive in certain circumstances. The agreements include provisions to accelerate the vesting of stock options subject to certain events including those related to a change in control. The Company entered into the August 2013 amendments to the foregoing agreements, upon recommendation by the Compensation Committee of the Board of Directors, to align the terms of certain termination benefits with termination terms for executive officers at similarly situated companies to the Company.

13. Quarterly Financial Information (Unaudited)

	First	Second	Third	Fourth
	(In thousands, except per share data)			
Year Ended December 31, 2014				
Grant and licensing revenue	$ 334	$ 212	$ 2,801	$ 169,245
Income (loss) from operations	(9,304)	(9,127)	(13,026)	149,030
Net income (loss)	(9,236)	(9,163)	(5,598)	126,855
Basic earnings (loss) per share	(0.33)	$ (0.66)	$ (0.86)	$ 4.54
Diluted earnings (loss) per share	$ (0.33)	$ (0.66)	$ (0.86)	$ 4.05
Year Ended December 31, 2013				
Grant and licensing revenue	$ 302	$ 232	$ 265	$ 294
Loss from operations	(8,042)	(7,069)	(8,117)	(7,913)
Net loss	(7,934)	(7,077)	(8,123)	(8,046)
Basic earnings (loss) per share	(0.33)	(0.28)	(0.32)	(0.31)
Diluted earnings (loss) per share	$ (0.33)	$ (0.28)	$ (0.32)	$ (0.31)

14. Subsequent Events

On February 27, 2015, the Company received $20.0 million in milestone payments from Merck after notification from Merck that the milestone event specified in the license and collaboration agreement between the two companies relating to the further development of the rVSV-EBOV (Ebola) vaccine product candidate had been achieved. The milestone pertains to the initiation of a key clinical trial for the vaccine.

On March 9, 2015, the Company entered into a contract with the United States Defense Threat Reduction Agency, or DTRA, securing funding of $6.4 million related to the advancement of the Company's Ebola vaccine product candidate. This contract definitizes the previous letter agreement which was entered into during August, 2014.

Subsequent to December 31, 2014 and through March 4, 2015, the Company sold an additional 329,402 shares of common stock under the ATM Offering, raising an additional $13.6 million in net proceeds.

Index to Exhibits

The following exhibits are filed with this form 10-K or incorporated herein by reference to the document set forth next to the exhibit listed below. Where so indicated, exhibits that were previously filed are incorporated by reference.

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3		Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1		Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2		Reference is made to Exhibits 3.1, 3.2 and 3.3				
4.3		Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.2	†	Form of Indemnity Agreement by and between the Registrant and its directors and executive officers	S-1/A	11/8/2011	10.11	
10.3	†	2000 Equity Incentive Plan	S-1	12/21/2010	10.2	
10.4.1	†	Form of Stock Option Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.3	
10.4.2	†	Form of Stock Option Grant Notice under 2000 Equity Incentive Plan	S-1	12/21/2010	10.4	
10.4.3	†	Form of Stock Bonus Agreement under 2000 Equity Incentive Plan	S-1	12/21/2010	10.5	
10.5	†	Amended and Restated 2009 Equity Incentive Plan	S-1	12/21/2010	10.6	
10.5.1	†	Form of Stock Option Agreement under 2009 Equity Incentive Plan	S-1	12/21/2010	10.7	
10.5.2	†	Form of Stock Option Grant Notice under 2009 Equity Incentive Plan	S-1	12/21/2010	10.8	
10.5.3	†	Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.6	
10.5.4	†	Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.7	
10.5.5	†	Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended	10-Q	8/5/2014	10.8	
10.6	†	2010 Employee Stock Purchase Plan	8-K	5/14/2013	10.2	
10.7	†	2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.3	
10.7.1	†	Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.4	
10.7.2	†	Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended	10-Q	8/5/2014	10.5	
10.8	†	Employment Agreement, dated as of December 6, 2010, by and between the Registrant and Charles J. Link, Jr.	S-1	12/21/2010	10.12	
10.9	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Nicholas N. Vahanian	S-1	12/21/2010	10.13	
10.10	†	Employment Agreement, dated as of June 26, 2008, by and between the Registrant and Gordon H. Link, Jr.	S-1	12/21/2010	10.14	
10.11	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Gordon H. Link, Jr.	S-1	12/21/2010	10.15	
10.12	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and Kenneth Lynn	S-1	12/21/2010	10.16	
10.13	†	Employment Agreement, dated as of November 22, 2010, by and between the Registrant and W. Jay Ramsey	S-1	12/21/2010	10.17	
10.14	†	Form of Employee Proprietary Information and Inventions Agreement	S-1	12/21/2010	10.18	
10.15	†	Promissory Note dated May 2, 2008 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.19	
10.16	†	Promissory Note dated April 18, 2000 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.20	

10.17	†	Promissory Note dated August 20, 2008 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.21
10.18	†	Promissory Note dated July 2008 by and between the Registrant and Gordon Link	S-1/A	2/28/2011	10.22
10.19	†	Amendment Agreement dated July 1, 2010 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.23
10.20	†	Amendment Agreement dated July 1, 2010 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.24
10.21	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Charles Link	S-1/A	2/28/2011	10.25
10.22	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Nicholas Vahanian	S-1/A	2/28/2011	10.26
10.23	†	Acknowledgment Agreement dated November 24, 2010 by and between the Registrant and Gordon Link	S-1/A	2/28/2011	10.27
10.24	†	Acknowledgment Agreement dated November 24, 2010 by and between BioProtection Systems Corporation and Charles Link	S-1/A	2/28/2011	10.28
10.25	†	Acknowledgment Agreement dated November 23, 2010 by and between BioProtection Systems Corporation and Nicholas Vahanian	S-1/A	2/28/2011	10.29
10.26	*	License Agreement dated July 7, 2005 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.30
10.26.1	*	First Amendment to License Agreement dated May 22, 2006 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.31
10.26.2	*	Second Amendment to License Agreement September 11, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.32
10.27	*	Exclusive License Agreement executed December 21, 2007 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.33
10.28	*	Exclusive License Agreement effective April 23, 2009 by and between the Registrant and Lankenau Institute for Medical Research	S-1/A	11/8/2011	10.34
10.29	*	License Agreement dated October 13, 2004 by and between the Registrant and Drexel University	S-1/A	11/8/2011	10.36
10.30	*	License Agreement dated August 2, 2001 by and between the Registrant and Central Iowa Health System	S-1/A	11/8/2011	10.37
10.31	*	License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46
10.31.1	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47
10.31.2	*	Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48
10.31.3	*	Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49
10.31.4	*	Amendment to License Agreement dated March 28, 2006 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.3
10.31.5	*	Amendment to License Agreement dated July 10, 2014 by and between the Company and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4
10.32	*	Patent License Agreement dated March 1, 2006 by and between the Registrant and Bresagen Xenograft Marketing Ltd.	S-1/A	11/8/2011	10.50
10.33	*	Exclusive License Agreement dated July 29, 2008 by and between the Regents of the University of California and BioProtection Systems Corporation	S-1/A	11/8/2011	10.66
10.34	*	Sole License Agreement executed May 4, 2010 by and between Public Health Agency of Canada in Right of Canada and BioProtection Systems Corporation	S-1/A	11/8/2011	10.67
10.34.1		Amendment dated July 31, 2014 to the Sole License Agreement by and between BioProtection Systems Corporation and Public Health Agency of Canada as Represented by the Minister of Health dated May 4, 2010	10-Q	11/10/2014	10.5
10.35	*	Letter of Intent for Cooperative Research and Development Agreement (CRADA #2166) dated May 7, 2007 by and between the Registrant and National Cancer Institute	S-1/A	11/8/2011	10.38

10.35.1	Amendment No. 1 to Letter of Intent for CRADA #2166 dated January 17, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.39
10.35.2	Amendment No. 2 to Letter of Intent for CRADA #2166 dated July 7, 2008 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.40
10.35.3	Amendment No. 3 to Letter of Intent for CRADA #2166 dated March 24, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.41
10.35.4	Amendment No. 4 to Letter of Intent for CRADA #2166 dated October 28, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.42
10.35.5	Amendment No. 5 to Letter of Intent for CRADA #2166 dated December 16, 2009 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.43
10.35.6	Amendment No. 6 to Letter of Intent for CRADA #2166 dated June 29, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.44
10.35.7	Amendment No. 7 to Letter of Intent for CRADA #2166 dated November 26, 2010 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.45
10.35.8	Amendment No. 8 to Letter of Intent for CRADA #2166 dated June 2, 2011 by and between the Registrant and National Cancer Institute	S-1/A	10/4/2011	10.79
10.36	Lease dated September 1, 2000 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.46
10.37	Sublease Agreement effective February 1, 2001 by and between the Registrant and Iowa State Innovation System	S-1	12/21/2010	10.47
10.38	Memorandum of Agreement dated December 6, 2005 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.48
10.39	Memorandum of Agreement dated April 13, 2006 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.49
10.40	Memorandum of Agreement dated February 20, 2008 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.50
10.41	Memorandum of Agreement dated May 1, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.51
10.42	Memorandum of Agreement dated March 24, 2010 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.52
10.43	Lease dated September 30, 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.53
10.44	Lease dated August 10, 2005 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.82
10.45	Memorandum of Agreement dated September 29, 2011 by and between the Registrant and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.84
10.46	Memorandum of Agreement dated September 29, 2011 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	S-1/A	10/26/2011	10.83
10.47	Memorandum of Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Iowa State University Research Park Corporation	8-K	11/18/2011	10.1
10.48	Promissory Note executed in 2009 by and between the Registrant and Iowa State University Research Park Corporation	S-1	12/21/2010	10.54
10.49	Forgivable Loan Agreement dated March 10, 2010 by and between the Registrant and City of Ames, Iowa	S-1	12/21/2010	10.55
10.50	Iowa Values Fund Agreement dated March 18, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.56
10.51	Master Contract dated December 29, 2005 by and between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.58
10.52	Contract Amendment dated April 21, 2009 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.59
10.53	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.57
10.54	Contract Amendment dated August 19, 2010 between the Registrant and Iowa Department of Economic Development	S-1	12/21/2010	10.60
10.55	Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.77

10.56		Contract Amendment effective February 17, 2011 between the Registrant and Iowa Department of Economic Development	S-1/A	9/14/2011	10.78
10.57		Contract No. W911NF-08-C-0044 dated May 5, 2008 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.68
10.57.1		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	S-1/A	2/28/2011	10.69
10.58	*	Contract No. HDTRA1-09-C-0014 dated September 25, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	11/8/2011	10.70
10.58.1		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	S-1/A	10/4/2011	10.80
10.59		Contract No. W911NF-09-C-0072 dated July 31, 2009 by and between BioProtection Systems Corporation and the United States Department of Defense	S-1/A	2/28/2011	10.71
10.59.1		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	S-1/A	2/28/2011	10.72
10.60		Grant Number 5U01AI066327-05 issued August 26, 2009 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.73
10.61		Grant Number 1R43AI084350-01A1 issued April 6, 2010 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	2/28/2011	10.74
10.62		Grant Number 5R43AI084350-02 issued March 24, 2011 by and between BioProtection Systems Corporation and the National Institutes of Health	S-1/A	10/4/2011	10.81
10.63		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	S-1/A	2/28/2011	10.75
10.64		Certificate of Merger of BPS Merger Sub, Inc. into BioProtection Systems Corporation filed on January 7, 2011	S-1/A	2/28/2011	10.76
10.65		Standard Design-Build Agreement dated November 14, 2011 by and between NewLink Genetics Corporation and Story Construction Co.	8-K	11/18/2011	10.2
10.66		NewLink Genetics Corporation 401(k) Prototype Plan and Trust, effective as of January 1, 2005	8-K	3/12/2012	10.2
10.67		NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2005	8-K	3/12/2012	10.3
10.68		Material Modification to the NewLink Genetics Corporation 401(k) Adoption Agreement, effective as of January 1, 2011	8-K	3/12/2012	10.4
10.69		Settlement Agreement with the Iowa Economic Development Authority, effective as of March 26, 2013	8-K	3/28/2012	10.1
10.70	†	2012 Target Bonus Awards	8-K	3/28/2012	10.2
10.71	*	Cooperative Research and Development Agreement between the Company and the National Cancer Institute, effective as of March 27, 2012	10-Q	5/10/2012	10.6
10.72		Letter of Resignation of Executive Vice President of Business Development, effective as of June 27, 2012	10-Q	8/14/2012	10.2
10.73	†	Offer of Employment for Head of Business Development, effective as of July 26, 2012	10-Q	8/14/2012	10.3
10.74	†	2013 Salaries and Target Bonus Awards	8-K	11/7/2012	10.1
10.75	†	2012 Named Executive Officer Bonus Awards	8-K	12/21/2012	10.1
10.76		Underwriting Agreement, effective as of January 30, 2013	8-K	1/31/2013	1.1
10.77		Memorandum of Agreement dated May 7, 2012 by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/15/2013	10.1
10.78		Memorandum of Agreement dated May 7, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.2
10.79		Memorandum of Agreement dated November 6, 2012 by and between BioProtection Systems Corporation and Iowa State University Research Park Corporation	10-K	3/15/2013	10.3

10.80	†	2013 Target Bonus Awards	8-K	4/5/2013	10.1	
10.81		Memorandum of Agreement dated April 15, 2013 by and between the Registrant and Iowa State University Research Park Corporation	10-Q	5/8/2013	10.1	
10.82		Story Construction Contract	10-Q	8/8/2013	10.1	
10.83		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation Dated March 1, 2010	10-Q	8/8/2013	10.2	
10.84	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Charles J. Link, Jr.	8-K	8/14/2013	10.1	
10.85	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Nicholas N. Vahanian	8-K	8/14/2013	10.2	
10.86	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and Gordon H. Link, Jr.	8-K	8/14/2013	10.3	
10.87	†	First Amendment to Employment Agreement, dated as of August 13, 2013, by and between Registrant and W. Jay Ramsey	8-K	8/14/2013	10.4	
10.88		Controlled Equity OfferingSM Sales Agreement, dated September 5, 2013, by and between NewLink Genetics Corporation and Cantor Fitzgerald & Co.	8-K	9/5/2013	10.1	
10.89		Amendment of Contract No. HDTRA1-09-C-0014, by and between BioProtection Systems Corporation and the United States Department of Defense, dated as of September 18, 2013	10-Q	11/12/2013	10.1	
10.90		License Agreement Amendment, by and between NewLink Genetics Corporation and Georgia Health Sciences University Research Institute, dated as of July 13, 2013	10-Q	11/12/2013	10.2	
10.91	†	2013 Bonus Awards	8-K	1/8/2014	10.1	
10.92	†	2014 Salaries, Bonus Targets and Equity Awards	8-K	1/8/2014	10.2	
10.93		Memorandum of Agreement, dated January 4, 2014, by and between the Registrant and Iowa State University Research Park Corporation	10-K	3/12/2014	10.93	
10.94	*	Amendment to License Agreement dated December 30, 2013, by and between Registrant and Central Iowa health System	10-K	3/12/2014	10.94	
10.95	†	Employment Agreement, dated as of March 11, 2014, by and between the Registrant and Brian Wiley	10-K	3/12/2014	10.95	
10.96	†	Employment Agreement, dated as of March 11, 2014, by and between the Registrant and Carl W. Langren	10-K	3/12/2014	10.96	
10.97	*	Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.1	
10.98	*	Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L HyperAcute Pancreas by and between the Company and WuXi AppTec, Inc. dated June 19, 2014	10-Q	8/5/2014	10.2	
10.99		Amendment dated September 30, 2014 to the Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec. Inc. dated June 19, 2014	10-Q	11/10/2014	10.2	
10.100		Separation and Release Agreement between the Company and Gordon H. Link, Jr., dated September 29, 2014	8-K	10/1/2014	10.1	
10.101		Offer Letter between the Company and Jack B. Henneman III, dated September 23, 2014	8-K	10/1/2014	10.2	
10.102	*	License and Collaboration Agreement dated October 16, 2014 by and among the Company, NewLink Global, Genentech, Inc. and F. Hoffmann-LaRoche Ltd.	10-Q	11/10/2014	10.1	
10.103	†	2014 Bonus Awards	8-K	1/6/2015	10.1	
10.104	†	2015 Salaries, Bonus Targets and Equity Awards	8-K	1/6/2015	10.2	
10.105	*	License and Collaboration Agreement dated November 21, 2014 by and among the Company, BioProtection Systems Corporation and Merck Sharp & Dohme Corp.				X
10.106		Memorandum of Agreement dated October 25, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated August 22, 2005				X
10.107		Memorandum of Agreement dated December 29, 2014; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010				X

10.108		Memorandum of Agreement dated February 12, 2015; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation dated March 1, 2010	X
21.1		Subsidiary Information	X
23.1		Consent of KPMG LLP, independent registered public accounting firm	X
24.1		Power of Attorney (included on signature page hereto)	X
31.1		Rule 13a-14(a)/15d-14(a) Certification	X
31.2		Rule 13a-14(a)/15d-14(a) Certification	X
32.1	#	Section 1350 Certification	X
101.INS		XBRL Instance Document (filed electronically herewith)	
101.SCH		XBRL Taxonomy Extension Schema Document (filed electronically herewith)	
101.CAL		XBRL Taxonomy Extension Calculation Linkbase Document (filed electronically herewith)	
101.LAB		XBRL Taxonomy Extension Label Linkbase Document (filed electronically herewith)	
101.PRE		XBRL Taxonomy Extension Presentation Linkbase Document (filed electronically herewith)	
101.DEF		XBRL Taxonomy Extension Definition Linkbase Document (filed electronically herewith)	

---

† 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 19434, as amended.

The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

Exhibit 10.105

EXECUTION COPY

LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this "**Agreement**") is effective as of November 21, 2014 (the "**Effective Date**"), and is entered into by and between **MERCK SHARP & DOHME CORP.**, a corporation organized and existing under the laws of New Jersey ("**Merck**"), and **BIOPROTECTION SYSTEMS CORPORATION,** a corporation organized and existing under the laws of Delaware ("**NewLink**") and a wholly owned subsidiary of **NEWLINK GENETICS CORPORATION**, a corporation organized and existing under the laws of Delaware ("**NL**"), and for purposes of Section 10.19, NL.

RECITALS:

WHEREAS, NewLink is currently developing a rVSV-EBOV (Ebola) vaccine; and

WHEREAS, NewLink and Merck desire to enter into a collaboration in order to research, develop, manufacture and commercialize Compounds (as hereinafter defined) and Products (as hereinafter defined), upon the terms and conditions set forth herein; and

WHEREAS, NewLink desires to grant to Merck licenses under the NewLink Patent Rights (as hereinafter defined) and NewLink Know-How (as hereinafter defined) to research, develop, manufacture and commercialize Compounds and Products upon the terms and conditions set forth herein.

NOW, **THEREFORE**, in consideration of the foregoing premises and the mutual covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, Merck and NewLink hereby agree as follows:

Article 1 DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below.

1.1 "**AAA**" shall have the meaning given to such term in Section 10.6.1.

1.2 "**Act**" means, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., in each case, as such may be amended from time to time.

1.3 "**Affiliate**" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses the power to direct or cause the direction of the management, business and policies of such Person, whether through the ownership of more than fifty percent (50%) of the voting securities of such Person, by contract or otherwise.

1.4 "**Agreement**" shall have the meaning given to such term in the preamble.

1.5 "**Agreement Payments**" shall have the meaning given to such term in Section 5.6.1.

1.6 "**Alliance Manager**" shall have the meaning given to such term in Section 2.8.

1.7 "**Alternative Product**" shall have the meaning given to such term in Section 8.2.2.

1.8 "**Applicable Laws**" means any and all applicable laws of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions, including the Act and GLPs, GCPs and GMPs.

1.9 "[*****]" shall have the meaning given to such term in Section 3.10.3.

1.10 "**Biosimilar Application**" shall have the meaning given to such term in Section 7.4.5(b).

1.11 "**BLA**" means a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, Premarket Approval Application or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.12 "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (i) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (ii) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the date of expiration or termination of this Agreement.

1.13 "**Calendar Year**" means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, however, that (i) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (ii) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of expiration or termination of this Agreement.

1.14 "**Change of Control**" means, with respect to Merck, NL or NewLink, as applicable, a transaction with a Third Party(ies) involving, (i) the acquisition, merger or consolidation, directly or indirectly, of Merck, NL or NewLink, as applicable, and, immediately following the consummation of such transaction, the shareholders of Merck, NL or NewLink, as applicable, immediately prior thereto hold, directly or indirectly, as applicable, shares of capital stock of the surviving company representing less than fifty percent (50%) of the outstanding shares of such surviving or continuing company, (ii) the sale of all or substantially all of the assets or business of Merck, NL or NewLink, as applicable, or (iii) a Person, or group of Persons acting in concert, acquire more than fifty percent (50%) of the voting equity securities or management control of Merck, NL or NewLink, as applicable.

1.15 "**Clinical Trial**" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, and/or post-regulatory approval clinical trial involving human subjects.

1.16 "**Code**" shall have the meaning given to such term in Section 8.3.3.

1.17 "**Combination Product**" means a Product which includes one or more Compound(s) in combination with one or more active ingredients other than such Compound(s), [*]; provided, however, nothing contained in this Agreement shall be interpreted as a grant of a license by NewLink to Merck to any other proprietary active compounds of NewLink (other than Compounds).

1.18 "**Commercialize**" means to promote, market, distribute, sell and provide product support for a Product, and "**Commercializing**" and "**Commercialization**" shall have correlative meanings.

1.19 "**Commercially Reasonable Efforts**" means with respect to the efforts to be expended by a Party with respect to any objective, the [*]. It is understood and agreed that with respect to the Development, Manufacture and Commercialization of Product by either Party, such efforts [*] and [*] taking into account [*] and other [*]. Commercially Reasonable Efforts shall be [*], and it is [*], and [*].

1.20 "**Competitor**" shall have the meaning given to such term in Section 10.2.3.

1.21 "**Compound**" means (i) the Current Compound and (ii) [*], including [*], in each case, [*], and in each case of this clause (ii) [*].

1.22 "**Confidential Information**" means any and all proprietary Know-How, information and data, including scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by or on behalf of one Party to the other Party and/or its Affiliate in connection with this Agreement.

1.23 "**Control**", "**Controls**" or "**Controlled by**" means, with respect to any Patent Rights, Know-How or other intellectual property assets or rights, as applicable, the possession of (whether by ownership or license or other right, other than pursuant to this Agreement) or the ability of a Party to grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.

1.24 "**Covered by**" or "**Cover**" or the like, means, with respect to a given Product in a given country, that [*] is claimed by a Valid Claim in such country and such Valid Claim would be infringed by the sale of such Product in such country but for the licenses granted to Merck hereunder; provided, that [*] for which [*] has been [*], and [*] is actually [*].

1.25 "**Critical Issue**" shall have the meaning given to such term in Section 2.7.2.

1.26 "**Current Compound**" means the [*] vaccine candidate known as rVSV-EBOV and more particularly described on Schedule 1.26.

1.27 "**Current Product**" means the [*] or [*] containing the Current Compound [*] or any [*], as the [*], for the treatment of Ebola [*] other than [*], but excluding, for clarity, [*].

1.28 "**Current Product Commercially Reasonable Efforts Obligation**" shall have the meaning given to such term in Section 3.5.1.

1.29 "[*****]" shall have the meaning given to such term in [*].

1.30 "**Develop**" means to research, develop, analyze, test and conduct preclinical, clinical and all other regulatory trials for Compound or a Product, as well as any and all activities pertaining to manufacturing development, formulation development, manufacturing scale-up and lifecycle management, including new indications, new formulations and all other activities related to securing and maintaining Marketing Authorization for a Product,

including pre- and post-Marketing Authorization regulatory activities in connection with a Product. "**Developing**" and "**Development**" shall have correlative meanings.

1.31 "**Dollar**" or "**$**" means United States dollars.

1.32 "**Effective Date**" shall have the meaning given to such term in the preamble.

1.33 "**EU**" or "**European Union**" means (a) the European Union and its member states as of the Execution Date, which are: Austria, Belgium, Bulgaria, Croatia, Cyprus , Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom, and (b) each of their successors to the extent such successors occupy the same territory and are included as part of the European Union.

1.34 "**Excluded Claim**" shall have the meaning given to such term in Section 10.6.6.

1.35 "**Existing Confidentiality Agreement**" means that certain Confidential Disclosure Agreement, dated [*], between Merck and NewLink.

1.36 "**Existing IND**" shall have the meaning given to such term in Section 2.9.2.

1.37 "**FDA**" means the United States Food and Drug Administration or any successor governmental authority having substantially the same function.

1.38 "**Field**" means any and all uses or purposes, including the treatment, palliation, diagnosis or prevention of any human or animal disease, disorder or condition.

1.39 "**First Commercial Sale**" means, with respect to a Product in a given country in the Territory, the first shipment to a Third Party of commercial quantities of such Product sold in such country to such Third Party on arm's length terms by Merck, its Affiliate or sublicensee for end use or consumption of such Product in the Field in such country (following, in all cases, the receipt of Marketing Authorization for such Product in such country). For clarity, First Commercial Sale shall be determined on a Product-by-Product basis.

1.40 "**GAVI Alliance**" means the Global Alliance for Vaccines and Immunization (GAVI), an independent non-profit organization established under the laws of Switzerland, with the purpose of providing support for improvements of vaccinations and immunization in the poorest countries of the world.

1.41 "**GAVI Eligible Countries**" means [*], as such [*]; provided that in no event [*]. For the avoidance of doubt, [*] shall, following [*].

1.42 "**Good Clinical Practices**" or "**GCPs**" means then-current Good Clinical Practices as such term is defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.

1.43 "**Good Laboratory Practice**" or "**GLPs**" means then-current standards for laboratory activities for pharmaceuticals or biologicals, as applicable, as defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.

1.44 "**Good Manufacturing Practices**" or "**GMPs**" means then current Good Manufacturing Practices as such term is defined from time to time by the FDA and governmental authorities in the European Union, pursuant to its regulations, guidelines or otherwise.

1.45 "**Human Materials**" shall have the meaning given to such term in Section 2.3.2.

1.46 "**IND**" means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.47 "**Indemnified Party**" shall have the meaning given to such term in Section 9.1.3.

1.48 "**Indemnifying Party**" shall have the meaning given to such term in Section 9.1.3.

1.49 "**Initiation**" means, with respect to a Clinical Trial, the administration of the first dose of the Current Product (or an Alternative Product, as applicable) to a properly enrolled patient in such Clinical Trial.

1.50 "**Insolvency Event**" shall have the meaning given to such term in Section 8.3.1(b).

1.51 "**Inventory**" shall have the meaning given to such term in Section 2.9.3(a).

1.52 "**Joint Program Know-How**" shall have the meaning given to such term in Section 7.2.1(c).

1.53 "**Joint Program Patent Rights**" shall have the meaning given to such term in Section 7.2.1(c).

1.54 "**Joint Steering Committee**" or "**JSC**" means the joint steering committee established to oversee the activities hereunder as more fully described in Section 2.6.

1.55 "**Know-How**" means any and all proprietary information and materials, including discoveries, improvements, processes, methods, protocols, formulas, molecular constructs,

cell lines, reagents, assays, data, seeds (including pre-seeds, master seeds and working seeds), cell banks (including master cell banks and working cell banks), clones, primers, vectors, antibodies, serum samples, biological samples, results, inventions, know-how, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise.

1.56 "**Liabilities**" shall have the meaning given to such term in Section 9.1.1.

1.57 "**Manufacture**" or "**Manufacturing**" means, with respect to a compound or product, including a Compound, Product and any other active pharmaceutical ingredient in a Product, the receipt, handling and storage of active pharmaceutical ingredients and other materials, the manufacturing, processing, packaging and labeling (excluding the development of packaging and labeling components for Marketing Authorization), holding (including storage), quality assurance and quality control testing (including release and stability) of such compound or product (other than quality assurance and quality control related to development of the manufacturing process, which activities shall be considered Development activities) and shipping of such compound or product.

1.58 "**Manufacturing Consultation**" shall have the meaning given to such term in Section 2.9.3(b).

1.59 "**Marketing Authorization**" means all approvals (including BLA approval, as applicable) from the relevant Regulatory Authority necessary to market and sell a Product in any country (including all applicable Price Approvals even if not legally required to sell Product in a country).

1.60 "**Merck**" shall have the meaning given to such term in the preamble.

1.61 "**Merck Background Know-How**" means all Know-How which (i) is in the Control of Merck or its Affiliates as of the Effective Date or during the Term, (ii) is not in the public domain, and (iii) [*]; provided, however, that Merck Background Know-How shall not include any Program Know-How.

1.62 "**Merck Background Patent Rights**" means Patent Rights that (i) are in the Control of Merck or its Affiliates as of the Effective Date or during the Term, and (ii) claim, cover or disclose Merck Background Know-How; provided, however that Merck Background Patent Rights shall not include any Program Patent Rights.

1.63 "**Merck Indemnitees**" shall have the meaning given to such term in Section 9.1.2.

1.64 "**Merck Know-How**" means (i) all Merck Background Know-How and (ii) all Merck Program Know-How Controlled by Merck or any of its Affiliates.

1.65 "**Merck Patent Rights**" means (i) all Merck Background Patent Rights and (ii) all Merck Program Patent Rights Controlled by Merck or any of its Affiliates.

1.66 "**Merck Program Know-How**" shall have the meaning given to such term in Section 7.2.1(b).

1.67 "**Merck Program Patent Rights**" shall have the meaning given to such term in Section 7.2.1(b).

1.68 "**Milestone Event**" shall have the meaning given to such term in Section 5.2.

1.69 "**Milestone Payment**" shall have the meaning given to such term in Section 5.2.

1.70 "**NewLink**" shall have the meaning given to such term in the preamble.

1.71 "**NewLink Canada License**" means, collectively, (i) that certain 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 ("**Public Health Canada**")) and NewLink, dated as of [*], and (ii) [*] between Public Health Canada and NewLink dated as of [*], in each case, as the foregoing may be further amended in accordance with Section 3.1.3.

1.72 "**NewLink Existing Funding Agreements**" means the agreements set forth on Schedule 1.72.

1.73 "**NewLink Existing Manufacturing Agreements**" means the agreements set forth on Schedule 1.73.

1.74 "**NewLink Existing Third Party Agreements**" means (i) the NewLink Canada License, (ii) the NewLink Existing Manufacturing Agreements, and (iii) the NewLink Existing Funding Agreements.

1.75 "**NewLink Funding Agreements**" shall have the meaning given to such term in Section 3.10.1.

1.76 "**NewLink Future Funding Agreements**" shall have the meaning given to such term in Section 3.10.1.

1.77 "**NewLink Indemnitees**" shall have the meaning given to such term in Section 9.1.1.

1.78 "**NewLink Know-How**" means all Know-How which (i) is in the Control of NewLink or its Affiliates as of the Effective Date or during the Term (subject to Section 10.2), (ii) is not in the public domain, and (iii) [*] is otherwise [*]. For the avoidance of doubt, NewLink Know-How shall include (x) any and all Know-How licensed under the NewLink Canada License, (y) all NewLink Program Know-How and (z) NewLink's interest in any Joint Program Know-How.

1.79 "**NewLink Patent Rights**" means Patent Rights that (i) are in the Control of NewLink or its Affiliates as of the Effective Date or during the Term (subject to Section 10.2), and (ii) (a) claim, cover or disclose [*], and/or (b) claim, cover or disclose any NewLink Know-How. The NewLink Patent Rights shall include the Patent Rights identified in Schedule 1.79 as well as any Patent Rights licensed under the NewLink Canada License. Schedule 1.79 may be updated by the Parties from time to time as provided in Section 3.2. NewLink Patent Rights shall include (x) NewLink Program Patent Rights and (y) NewLink's interest in any Joint Program Patent Rights.

1.80 "**NewLink Program Know-How**" shall have the meaning given to such term in Section 7.2.1(a).

1.81 "**NewLink Program Patent Rights**" shall have the meaning given to such term in Section 7.2.1(a).

1.82 "**NewLink Third Party Agreements**" means (i) the NewLink Existing Third Party Agreements, (ii) any other agreements [*] relating to the Development, Manufacture, Commercialization or other exploitation of Compounds or Products, including any agreements [*] or the [*], and (iii) any NewLink Funding Agreement [*] and any agreement included on Schedule 3.10.

1.83 "**NIH-Liberia Clinical Trial**" means the Clinical Trial which is [*], and which [*].

1.84 "**Officials**" shall have the meaning given to such term in Section 2.5.2.

1.85 "**Other Product Commercially Reasonable Efforts Obligation**" shall have the meaning given to such term in Section 3.5.1.

1.86 "[*****]" shall have the meaning given to such term in [*].

1.87 "**Party**" means Merck or NewLink, individually, and "**Parties**" means Merck and NewLink, collectively.

1.88 "**Payment**" shall have the meaning given to such term in Section 2.5.2.

1.89 "**Patent Rights**" means any and all patents and patent applications in the Territory (which for the purpose of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

1.90 "**Person**" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.91 "**Phase I Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).

1.92 "**Phase II Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).

1.93 "**Phase III Clinical Trial**" means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).

1.94 "**Pivotal Clinical Trial**" means the first to occur of (i) [*] or (ii) [*] which is [*] of the [*] for clarity, any [*].

1.95 "**Price Approvals**" means in countries in the Territory where Regulatory Authorities may approve or determine pricing or pricing reimbursement for pharmaceutical products, such approval or determination.

1.96 "**Product**" means any pharmaceutical composition or preparation (in any and all dosage forms) in final form containing a Compound, [*]. For clarity, except with respect to [*], different [*] for the purposes of this Agreement.

1.97 "**Product Diligence Obligations**" shall have the meaning given to such term in Section 3.5.1.

1.98 "**Product Materials**" shall have the meaning given to such term in Section 6.2.21.

1.99 "**Product Net Sales**" means the gross invoice price (not including value added taxes, sales taxes, or similar taxes) of Product in the Royalty Bearing Territory for use in the Field sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received:

(a) [*];

(b) [(];

(c) [*] that are [*];

(d) [*]; or any other [*]; provided, that for clarity, nothing in this clause (d) shall be deemed to exclude [*] to the [*];

(e) [*];

(f) [*], including [*]; provided that any such [*];

(g) [*] of the [*] and [*]; and

(h) [*].

Product Net Sales shall not include [*].

With respect to sales of Combination Products, Product Net Sales shall be calculated on the basis of [*]. In the event that a Product is sold only as a Combination Product, Product Net Sales shall be calculated on the basis of [*] and the [*]. [*] shall be determined [*]. The deductions set forth above will be applied in calculating Product Net Sales for a Combination Product. In the event that a Product is sold only as a Combination Product and [*] to the [*], the Parties shall [*].

1.100 "**Program Know-How**" means any Know-How (including any Compounds) that is first conceived, discovered, made and/or reduced to practice (as would be necessary to establish inventorship under United States patent law (regardless of where the applicable activities occurred)) by or on behalf of either Party or its Affiliate (or their respective employees, agents or consultants) or jointly by both Parties or their respective Affiliates (or their respective employees, agents or consultants) in performing the Transition Program or other activities under this Agreement.

1.101 "**Program Patent Rights**" means any and all Patent Rights that claim, cover or disclose Program Know-How.

1.102 "**Project Leader**" shall have the meaning given to such term in Section 2.8.

1.103 "**Prosecute**" means, in relation to any Patent Rights, (i) to prepare and file patent applications, including re-examinations or re-issues thereof, and represent applicant(s) or assignee(s) before relevant patent offices or other relevant authorities during examination, re-examination and re-issue thereof, in appeal processes and interferences, oppositions or any equivalent proceedings, (ii) to secure the grant of any Patent Rights arising from such patent application, (iii) to maintain in force any issued Patent Right (including through

payment of any relevant maintenance fees), and (iv) to make all decisions with regard to any of the foregoing activities. "**Prosecution**" has a corresponding meaning.

1.104 "**Providers**" shall have the meaning given to such term in Section 2.3.2.

1.105 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a pharmaceutical product in the Territory, including, in the United States, the FDA.

1.106 "**Regulatory Documentation**" shall have the meaning given to such term in Section 2.9.2.

1.107 "**Related Party**" means each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

1.108 "**Royalty Bearing Territory**" means the Territory excluding [*] and [*].

1.109 "**Royalty Term**" shall have the meaning given to such term in Section 5.4.2.

1.110 "**rVSV**" means the replication-competent recombinant vesicular stomatitis virus vector system.

1.111 "**Safety Termination**" shall have the meaning given to such term in Section 8.2.1.

1.112 "**Sensitive Information**" shall have the meaning given to such term in Section 10.2.3.

1.113 "**Term**" shall have the meaning given to such term in Section 8.1.

1.114 "**Terminated Products**" shall have the meaning given to such term in Section 8.3.2(a).

1.115 "**Territory**" means worldwide, including all of the countries in the world, and their territories and possessions.

1.116 "**Third Party**" means a Person other than Merck and its Affiliates, NL and its Affiliates and NewLink and its Affiliates.

1.117 "**Third Party Claim**" shall have the meaning given to such term in Section 9.1.1.

1.118 "**Third Party Funding Sources**" means Third Party funding sources, including [*] and [*] with respect to the Development, Manufacture and/or Commercialization of Compound and/or Product.

1.119 "**Transfer Taxes**" shall have the meaning given to such term in Section 5.6.1.

1.120 "**Transition Period**" shall mean the period commencing on the Effective Date and ending upon the later to occur of (i) completion of all activities under the Transition Plan, or (ii)

[*]; provided that in no event shall the Transition Period end later than [*] unless [*], as applicable, [*], in which case the Transition Period shall continue [*], until such time as [*] in accordance with the terms of this Agreement.

1.121 "**Transition Plan**" means the plan for transitioning [*] activities with respect to [*] from NewLink to Merck, as such plan is established by the JSC in accordance with this Agreement, and as such plan may be updated from time to time in accordance with this Agreement.

1.122 "**Transition Plan Outline**" means the outline for the plan for transitioning [*] activities with respect to Compound and Product as set forth on Schedule 1.122.

1.123 "**Transition Program**" means the conduct of certain ongoing [*] activities by or on behalf of NewLink with respect to [*], and the transition of such activities to Merck, as set forth in Article 2 and in the Transition Plan.

1.124 "**Tri-Party Confidentiality Agreement**" means that certain Confidentiality and Non-Disclosure Agreement, dated [*], between Public Health Canada, Merck, NewLink and NL.

1.125 "**Valid Claim**" means a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension) within the NewLink Patent Rights, which claim has not been abandoned or revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period), and has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

1.126 "**Violation**" means that a Party or any of its officers or directors or any other NewLink personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); or (3) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the "**Exclusions Lists**").

ARTICLE 2TRANSITION PROGRAM

2.1 **General**. Each Party, at such Party's cost, shall engage in the Transition Program upon the terms and conditions set forth in this Agreement, including performing all activities to be performed by such Party as set forth in the Transition Plan.

2.2 **Transition Plan; Conduct of Transition Program**. Within [*] after the Effective Date, the Parties shall establish the initial Transition Plan which shall be based on the Transition Plan Outline. Each Party shall, [*] perform its activities under the Transition Program, including by using its good faith, diligent efforts to allocate sufficient time, effort, equipment and facilities to the Transition Program and to use personnel with sufficient skills and experience as are required to accomplish the Transition Program in accordance with the terms of this Agreement and the Transition Plan, as applicable. Merck shall be prepared to receive, and NewLink shall promptly deliver to Merck, [*] pursuant to and as set forth in the Transition Plan or [*]. In performing activities under the Transition Program, NewLink shall consult with Merck and shall [*] with respect to the activities conducted under the Transition Program, including [*], subject to Section 3.10.2 with respect to the activities under NewLink Funding Agreements and subject to Section 2.7.2 with respect to amendments of the Transition Plan.

2.3 **Compliance; Additional Requirements**.

2.3.1 **General**. Each Party shall conduct its activities hereunder, including activities under the Transition Program and activities under the NewLink Funding Agreements, in compliance with all Applicable Laws. Each Party shall notify the other in writing of any deviations from Applicable Laws. In addition, each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the Transition Program or other activities under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall notify the other in writing immediately if any such suspension, proposed debarment or debarment occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment or debarred, promptly remove such Person from performing any Transition Program activities, function or capacity related to the Transition Program or any other activities under this Agreement (including activities under the NewLink Funding Agreements).

2.3.2 **Use of Human Materials**. Without limiting the provisions of Section 2.3.1, if any human cell lines, serum samples, biological samples, tissue, human clinical isolates or similar human-derived materials ("**Human Materials**") have been or are to be collected and/or used in the Transition Program (or under the NewLink Funding Agreements), NewLink represents and warrants (i) that it has complied, and shall comply, with all Applicable Laws relating to the collection and/or use of the Human Materials and (ii) that it has obtained, and shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. NewLink shall provide documentation of such approvals and consents upon Merck's request. NewLink further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities ("**Providers**") who contributed the Human Materials, including any obligations of compensation to such Providers or any other Third Party for the intellectual property associated with, or commercial use of, the Human Materials for any purpose.

2.3.3 **Use of Third Party Intellectual Property**. In performing activities under the Transition Program (or activities under the NewLink Funding Agreements), [*] shall not (i) incorporate any Know-How or other intellectual property owned by any Third Party into any Compound, Product or other Program Know-How or (ii) otherwise use any Know-How or other intellectual property owned by any Third Party in the performance of the Transition Program (or activities under the NewLink Funding Agreements). Notwithstanding the foregoing, [*] shall be allowed to [*] under the [*] to perform the Transition Program.

2.3.4 **Clinical Trial-related Adverse Events**. With respect to Clinical Trials being carried out by or on behalf of a Party for the Current Product during the Transition Period, serious adverse experience reports as defined in 21 CFR 312.32 must be forwarded to the other Party within [*] after receipt of the information. In addition, each Party shall furnish to the other Party copies of the end of study summary of adverse experiences in English as promptly as possible following completion of such Clinical Trial (or earlier, as reasonably requested by such other Party). Within [*] after the Effective Date, NewLink and Merck (or its Affiliate) shall enter into a pharmacovigilance agreement in order to share safety information and satisfy related requirements of Regulatory Authorities and Applicable Law with respect to Compounds and Products.

2.4 **Use of Third Parties**. Each Party shall be entitled to utilize the services of Third Parties to perform its activities hereunder; provided that [*] that are identified in [*] or [*] expand

the scope of activities being performed [*]. Notwithstanding the foregoing, each Party shall remain at all times responsible for the performance of its responsibilities under this Agreement, and shall ensure compliance with the applicable terms of this Agreement by any such Third Party, including (a) that such Third Party's employees involved in performing activities hereunder shall comply with the confidentiality provisions of this Agreement, (b) that such Third Party (including the employees of such Third Party) shall be obligated to assign any rights they may have in any Know-How and Patent Rights resulting from such activities in accordance with Section 7.2, and (c) that such Third Party shall comply with the terms of this Agreement applicable to the subcontracted activities, including Sections 2.3, 2.5 and 2.10. In addition, each Party hereby certifies that it has not retained or otherwise used in any capacity a Third Party, and will not retain or otherwise use in any capacity, the services of any Third Party suspended, proposed for debarment or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any portion of the activities under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall notify the other in writing immediately if any such suspension, proposed debarment or debarment occurs or comes to its attention, and shall, with respect to any Third Party or entity so suspended, proposed for debarment or debarred promptly remove such Third Party or entity from performing any activities, function or capacity under this Agreement (including activities under the NewLink Funding Agreements). Each Party shall oversee the performance by any such Third Parties it utilizes, and shall remain responsible for the performance of such activities in accordance with this Agreement (including activities under the NewLink Funding Agreements). Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance hereunder, prior to proceeding directly against the Party engaging the subcontractor.

2.5 **Compliance with Ethical Business Practices**.

2.5.1 **Compliance with Corporate Policy**. NewLink acknowledges that Merck's corporate policies require that business must be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the activities contemplated herein (including activities contemplated under the NewLink Funding Agreements) in a manner which is consistent with both law and good business ethics.

2.5.2 **Governments and International Public Organizations**. Without limitation of the foregoing, each Party warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, representatives of any government or international public organization. Each Party agrees that it shall not make any payment, either directly or indirectly, of money or other assets, including

to the compensation derived from this Agreement (hereinafter collectively referred as a "**Payment**"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "**Officials**") where such Payment would constitute a violation of any law. In addition, regardless of legality, a Party shall make no Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the other Party's businesses.

2.5.3 **No Authority**. Each Party acknowledges that no employee of the other Party or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by such Party or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.

2.5.4 **Exclusions Lists**. Each Party certifies to the other that as of the Effective Date it has screened itself, and its officers and directors, against the Exclusions Lists and that it has informed such other Party whether it, or any of its officers or directors has been in Violation. After the execution of this Agreement, each Party shall notify the other in writing immediately if any Violation occurs or comes to its attention, and shall, with respect to any person or entity in Violation, promptly remove such person or entity from performing any Transition Program activities, function or capacity related to the Transition Program or otherwise related to activities under this Agreement (including activities under the NewLink Funding Agreements).

2.6 **Joint Steering Committee**. The Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") to generally oversee the Transition Program, and to oversee [*].

2.6.1 **Composition of the JSC**. As soon as practicable, but in no event more than [*] after the Effective Date, the Parties will establish the JSC, which will be comprised of an equal number of representatives of each Party, with three (3) representatives of NewLink (who shall be employees of NewLink) and three (3) representatives of Merck (who shall be employees of Merck or its Affiliate); provided, however, that the Parties may agree to increase or decrease the number of equal representatives from each Party. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Parties' activities and interactions hereunder. Each Party may replace its representative(s) at any time upon prior notice to the other Party. The JSC will meet in person or by teleconference at

least [*] per [*] at a mutually acceptable date and location; provided, however, that it is the intent of the Parties that the JSC shall have more frequent and regular interaction [*] in order to facilitate the Transition Program. Each Party may, if approved by the other Party (such approval not to be unreasonably withheld), from time to time invite a reasonable number of participants, in addition to its representatives, to attend the JSC meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. The JSC will be chaired by a Merck representative. The role of the chairperson shall be to preside in person or telephonically at meetings of the JSC, to prepare and circulate agendas and to ensure the preparation of minutes. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval reasonably promptly after each JSC meeting. Such minutes will be deemed approved unless one or more of the members of the JSC objects to the accuracy of such minutes within [*] of receipt. Each Party shall bear its own expenses related to the attendance of such meetings by its representative(s).

2.6.2**Responsibilities**. The JSC shall:

(a) Review, oversee and direct the efforts, progress and status of the Transition Program (including technology transfer, if any), including reviewing and directing the conduct of the Transition Program;

(b) Review, oversee and direct the efforts, progress and status of [*];

(c) Review and approve amendments to the Transition Plan from time to time;

(d) Review [*] issues that arise in connection with [*], during the [*];

(e) Oversee and make decisions with respect to matters related to [*] in connection with Compound and Product; and

(f) Address such other matters relating to the activities under this Agreement designated to be addressed by the JSC under this Agreement or as either Party may otherwise bring before the JSC.

2.6.3**Subcommittees**. The JSC shall have the right to form subcommittees as determined by the JSC in order to address any particular matters within the authority of the JSC. For clarity, any such subcommittee shall have no broader rights and no broader authority than the JSC, and shall only exercise those rights and authorities as designated to such subcommittee by the JSC. Any such subcommittee shall have no decision making authority, but shall make recommendations to the JSC for the JSC's review and approval.

2.6.4**Disbandment of JSC**. The JSC shall be automatically disbanded (without any further actions by either Party) and shall have no further authority with respect to the activities hereunder, upon the end of the Transition Period. Thereafter, the JSC shall have no further obligations under this Agreement and the Project Leaders shall be the contact persons for the exchange of information under this Agreement.

2.6.5**Development Forums**. During the [*] period following the disbanding of the JSC in accordance with Section 2.6.4, the Parties shall meet in person or by teleconference no less than [*] to discuss Merck's Development of Products, including Products other than the Current Product (the "**Development Forum**"). At each such meeting, Merck will provide NewLink with an update on the status of the Development of the Products, and Merck's ongoing plan for the Development of Products (provided that, for clarity, such plan shall be non-binding and for informational purposes only). In addition, during such period, Merck will promptly notify NewLink if Merck suspends or otherwise terminates the Development or Commercialization of any Compound or Product.

2.7 **Scope of Committee Oversight and Decision-Making Authority**.

2.7.1**Scope of Committee Oversight**. The JSC shall not have the right to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement or (iv) following agreement with respect to the initial Transition Plan, amend the Transition Plan in a manner that would [*], unless such amendment is mutually agreed to by the Parties in writing; provided that, for the avoidance of doubt, if the work proposed in the amendment to the Transition Plan [*] or otherwise [*], then [*] such work and the [*].

2.7.2**Decision-Making Authority**. The goal of all decision-making of the JSC shall be to achieve consensus. All decisions of the JSC with respect to matters over which it has decision-making authority shall be made by unanimous vote of the applicable

committee's representatives, with each Party collectively having one (1) vote. However, in the event that the JSC is unable to reach consensus within [*] of the matter first being referred to the JSC, then [*], subject to [*], unless such matter is one of the following matters (each, a "**Critical Issue**"): (i) [*]; or (ii) [*]. If the Parties cannot agree on any Critical Issue, then the status quo of such matter shall continue; provided, however, with respect to a Critical Issue in (i) above, [*]. Any decision made by [*] must be consistent with the terms of this Agreement and within the scope of authority delegated to the JSC under this Agreement.

2.8 **Project Leads and Alliance Managers**. Merck and NewLink each shall appoint an employee of such Party (or its Affiliate, as applicable) as its project leader (the "**Project Leader**") who shall be the primary contact between the Parties with respect to the Transition Program and who shall coordinate each Party's role in the Transition Program. Each Party shall notify the other within [*] of the Effective Date of the appointment of its Project Leader and shall notify the other Party as soon as practicable upon changing this appointment. In addition, each Party may also appoint, at its discretion, an alliance manager to facilitate communications between the Parties hereunder (the "**Alliance Manager**"). If a Party appoints an Alliance Manager, such Party shall notify the other of the appointment of its Alliance Manager and shall notify the other Party as soon as practicable upon changing this appointment.

2.9 **Exchange of Information and Materials**.

2.9.1 **General**. As soon as reasonably practicable following Effective Date (but in all cases within [*] after the Effective Date or such other period of time as agreed to by the Parties), NewLink shall disclose to Merck in English (in writing and in an electronic format) all NewLink Know-How. Thereafter on an ongoing basis during the Term upon the reasonable request of Merck, NewLink shall cooperate with Merck and promptly disclose to Merck in English (and deliver in writing and in an electronic format) (i) any other NewLink Know-How (including any Program Know-How) relating to Compound or Product (or the Development, Manufacture, use or Commercialization thereof) as may be developed or identified by or on behalf of NewLink (or its Affiliates), and (ii) from the Effective Date until [*], any other materials and documentation (including [*]) in NewLink's (or its Affiliate's or subcontractor's) possession or Control as may be reasonably requested by Merck from time to time that relate to Compounds or Products and are to be used by or on behalf of Merck in the performance of its activities under this Agreement, including [*]. Without limiting the generality of the foregoing, [*], NewLink shall [*] to provide [*] pursuant to, and in accordance with, [*].

2.9.2**Technology Transfer; Transition of Activities**. As soon as reasonably practicable following the Effective Date (but in all cases within [*] or such other period of time as agreed to by the Parties), NewLink shall (i) transfer to Merck (or its designee) all materials (other than Inventory) related to Compound or Product in NewLink's (or any of its Affiliate's or contractor's) possession or Control, including [*], and (ii) transfer and assign to Merck (or its designee), and NewLink hereby does transfer and assign to Merck, all Regulatory Documentation (other than the Existing IND) related to Compound or Product (including the transfer to Merck of a database that contains all relevant information regarding adverse events that have been observed during any clinical trials or studies with respect to Compound or Product prior to the Effective Date). In addition, upon Merck's request, NewLink shall transfer and assign to Merck (or its designee) [*] (the "**Existing IND**"). NewLink shall assist Merck, and each Party shall reasonably cooperate, to ensure [*], including providing [*] in connection therewith. As used herein, the term "**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals (including all Marketing Authorizations), all correspondence submitted to or received from Regulatory Authorities (including [*]) and all supporting documents in connection therewith, and all reports and documentation in connection with clinical studies and tests (including [*]), and [*] in any of the foregoing, including all INDs, BLAs, [*], in each case related to a Compound and/or Product.

2.9.3**Inventory Transfer and Manufacturing Technology Transfer**.

(a) Inventory Transfer. At the request of Merck from time to time as set forth in the Transition Plan, NewLink shall promptly transfer title to Merck and deliver to Merck (or its designee) (at a location to be [*]), [*] any or all (as and to the extent [*]) inventory of Compound and Product (including [*]) held by or on behalf of NewLink or any of its Affiliates (including any such inventory [*]) (the "**Inventory**").

(b) Manufacturing Technology Transfer. Without limiting the provisions of Sections 2.9.1 and 2.9.2, as soon as reasonably practicable following the Effective Date (but in all cases within [*] after the Effective Date or such other period of time as agreed to by the Parties), NewLink shall transfer or cause to be transferred (including from its Third Party contract manufacturers) to Merck or its Affiliate (or a Third Party manufacturer designated by Merck), copies in English (in writing and in an electronic format) of all [*] that is related to the manufacture of the Compounds and/or Products, in order to enable Merck (or its designee) to manufacture the Compounds and Products, including [*] to manufacture Compounds and Products, including [*]. In addition, at the request of Merck from time to time, NewLink shall make its (and its Affiliates') employees and consultants (including personnel of its

Third Party contract manufacturers) available to Merck to provide reasonable consultation and technical assistance in order to ensure an orderly transition of the manufacturing technology and operations to Merck (or its designee) and to assist Merck (or its designee) in the start-up of its manufacture of Compound and Product (such consultation, the "**Manufacturing Consultation**"). For clarity, the Manufacturing Consultation shall be [*].

2.9.4 **Assignment of Certain Existing Agreements**. At the written request of Merck, NewLink shall, to the extent legally permissible (and, to the extent consent is required from the relevant counterparty, [*]), (i) assign to Merck (or its Affiliate) any or all (as designated by Merck) of [*] and/or (ii) assist Merck (or its Affiliate) in [*] to cover the subject matter of such [*], as applicable, in each case of (i) and/or (ii), [*]; provided that NewLink shall not be obligated to assign any such [*] if such [*] is [*]. In the event that any [*] is assigned to Merck, NewLink shall [*], or related to, any such [*] as a result of, or in connection with, [*] of such [*], but which [*]. In the event that a given [*] is assigned to Merck in accordance with this Section 2.9.4, then such [*] shall [*].

2.9.5 **Transition and Transition Plan; Ongoing Assistance**. Without limiting the foregoing provisions of this Section 2.9, NewLink shall perform the activities to be performed by NewLink as set forth in the Transition Plan (including technology transfer). NewLink shall, during the period from the Effective Date [*], perform such other reasonable activities and provide such other reasonable assistance as Merck may reasonably request from time to time, in order to transition the Development, Manufacturing and Commercialization of Compound and Product to Merck and [*] Develop, Manufacture and Commercialize Compound and Product, including [*]; provided, that if Merck requests any such assistance after the end of the Transition Period, the Parties will agree on the scope and plan for such activities (including a plan for addressing the costs and expenses of such activities) prior to NewLink's performance thereof, [*].

2.9.6 **Data From Third Party Studies**. To the extent that any Development activities (including clinical trials) are being conducted by, or sponsored by, a Third Party (including [*]) with respect to Compound or Product, [*] to obtain [*], and to [*], including the [*].

2.9.7 **[*]**. The Parties agree and acknowledge that, except as expressly set forth in Section 2.9.5, the activities set forth in this Section 2.9, and any other activities [*], shall be [*].

2.10 **Records and Reports**.

2.10.1 **Records**. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Transition Program or other activities under this Agreement (including activities under the NewLink Funding Agreements).

2.10.2 **Copies and Inspection of Records; Reports**. Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records of NewLink referred to in Section 2.10.1. Merck shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employee(s) and/or consultant(s) involved in the activities contemplated hereunder to visit the offices and laboratories of NewLink and any of its Third Party contractors as permitted under Section 2.4 during normal business hours and upon reasonable notice, and to discuss work performed for the Transition Program [*] with the technical personnel and consultant(s) of NewLink. Upon the reasonable request of Merck, NewLink shall provide copies of such NewLink records described in Section 2.10.1.

2.10.3 **[*] Reports**. Within [*] following the end of each [*], NewLink shall provide to Merck a written progress report in English which shall summarize the work performed to date on the Transition Program [*] in relation to the [*] of the [*] and provide [*] by the [*] relating to the progress of the goals or performance of the Transition Program [*] under the [*]. NewLink shall use Commercially Reasonable Efforts to [*]. For clarity, all such reports shall be considered the Confidential Information [*].

2.10.4 **Data Integrity**. Each Party acknowledges the importance of ensuring that the Transition Program (and the activities under the NewLink Funding Agreements) is undertaken in accordance with the following good data management practices: (i) data is being generated using sound scientific techniques and processes; (ii) data is being accurately and reasonably contemporaneously recorded in accordance with good scientific practices by Persons conducting research hereunder; (iii) data is being analyzed appropriately without bias in accordance with good scientific practices; and (iv) all data and results are being stored securely and can be easily retrieved. Each Party agrees that it shall carry out the Transition Program (and activities under the NewLink Funding Agreements) so as to collect and record any data generated therefrom in a manner consistent with the foregoing requirements.

2.11 **Transition Program Costs**. [*] costs in connection with performing Transition Program activities.

ARTICLE 3 LICENSE, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

3.1 **License Grants by NewLink**.

3.1.1 **NewLink Patent Rights and NewLink Know-How**. Subject to the terms and conditions of Section 3.1.3, NewLink hereby grants to Merck an exclusive (even as to NewLink and its Affiliates), royalty-bearing license in the Territory under the NewLink Patent Rights and NewLink Know-How, with a right to grant and authorize sublicenses (subject to the restriction set forth below) through multiple tiers, to research, develop, make, have made, use, offer to sell, sell, import, export and/or otherwise exploit Compounds and Products in the Field. Merck may grant sublicenses of the rights granted to it under this Section 3.1.1 [*]; provided, however, that (a) promptly following the execution of any such sublicense for Commercialization rights with a Third Party, Merck shall [*], and (b) Merck shall be responsible for ensuring that the performance by any of its sublicensees hereunder that are exercising rights under a sublicense hereunder is in accordance with the applicable terms of this Agreement, and the grant of any such sublicense shall not relieve Merck of its obligations under this Agreement (except to the extent they are performed by any such sublicensee(s) in accordance with this Agreement).

3.1.2 **NewLink Retained Rights**. Notwithstanding the scope of the exclusive license granted to Merck under Section 3.1.1, subject to the terms and conditions of this Agreement, NewLink shall retain rights under the NewLink Patent Rights and the NewLink Know-How for the sole purpose of performing NewLink's obligations under the Transition Program in accordance with this Agreement and the Transition Plan and to perform activities expressly set forth in the NewLink Funding Agreements in accordance with this Agreement (including Section 3.10). NewLink shall [*].

3.1.3 **NewLink Canada License**. Notwithstanding anything to the contrary herein, all licenses or other grants granted by NewLink to Merck hereunder with respect to any NewLink Know-How or NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License shall at all times be subject to the terms and conditions of the NewLink Canada License. It is the intent of the Parties that [*], and as such, each Party hereby covenants that it shall [*] and shall [*] to include in [*] (provided that, [*] may also [*] that are not

[*], which [*] and the Parties [*]), and [*]. NewLink shall [*], it being understood that [*] this sentence to the extent [*] is [*] or the [*]; provided that [*].

3.2 **Non-Exclusive License Grant to Merck**. In the event that the research, development, making, having made, use, offer for sale, sale, import and/or other exploitation by Merck, or Merck's Related Parties, of Compound(s) or Product(s) would infringe a claim of an issued letters patent which NewLink (or its Affiliate) Controls and which patents are not covered by the grant in Section 3.1 (an "**Additional NewLink Patent**"), Merck or NewLink, as applicable, shall so notify the other Party thereof. Thereafter, (i) the Parties will [*] and (ii) such Additional NewLink Patent [*]. Notwithstanding the foregoing, if Merck notifies NewLink in writing that [*] shall [*] included in the [*] and shall [*]. Notwithstanding the foregoing, if the exercise by Merck of the license under Section 3.1 with respect to any Additional NewLink Patent would [*], such patent shall [*] for such [*] were notified by [*] at the time the Additional NewLink Patent [*]; provided, however, that [*] to [*] the [*].

3.3 **Non-Exclusive License Grants to NewLink**. If NewLink's performance of activities under the Transition Program requires a license under any Merck Patent Rights or under any Merck Know-How, as applicable, Merck shall grant and hereby grants to NewLink, a non-exclusive, non-transferable, non-sublicensable, royalty-free license under such Merck Patent Rights and/or Merck Know-How, as applicable, solely to perform such activities under the Transition Program in accordance with this Agreement. For clarity, the foregoing licenses set forth in this Section 3.3 shall not limit in any way the exclusive licenses granted to Merck under Section 3.1.

3.4 **No Grant of Inconsistent Rights by NewLink**. NewLink (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Person or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise) (i) any rights to any NewLink Know-How or NewLink Patent Rights (or any rights to any intellectual property that would otherwise be included in the NewLink Know-How or NewLink Patent Rights), in any manner that is inconsistent with or would interfere with the grant of the rights or licenses to Merck hereunder, or (ii) any rights to any Compounds or Products (provided that NewLink shall grant to Merck the rights to the Compounds and Products as set forth herein). Without limiting the foregoing, [*] any Compounds or Products [*], except for [*] to be [*] as set forth in the [*] shall not [*] to any Third Parties [*].

3.5 **Development, Manufacturing and Commercialization**.

3.5.1 **General**. Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to (and shall control all aspects of) Develop and Commercialize Compounds and Products in accordance with the terms of this

Agreement, and for clarity, [*] NewLink [*] to be [*] under the Transition Program in accordance with this Agreement and [*] expressly set forth in the [*]. With respect to the Current Product, Merck (and its Affiliates), either itself or with or through Third Party(ies), shall use Commercially Reasonable Efforts to Develop and, following receipt of all applicable Marketing Authorizations (if achieved), to Commercialize the Current Product (the "**Current Product Commercially Reasonable Efforts Obligation**"), and [*] Merck (and its Affiliates), either itself or with or through Third Party(ies), shall [*] use Commercially Reasonable Efforts [*], and, together with the Current Product Commercially Reasonable Efforts Obligation, the "**Product Diligence Obligations**"). [*] efforts and decisions with respect to the Compounds and Products [*]. Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to (and shall control all aspects of) Manufacture Compound and Product, and [*] NewLink [*] to be [*] under the Transition Program in accordance with this Agreement and [*] expressly set forth in the [*].

3.5.2 **Booking of Sales; other Commercialization**. Without limiting the generality of the provisions of Section 3.5.1, Merck (and its Affiliates), either itself or with or through Third Party(ies), shall have the sole right to, and shall control all aspects of, (i) handling all returns, recalls, order processing, invoicing and collection, distribution, inventory and receivables arising from sales to Third Parties, in each case, with respect to Product, (ii) booking of sales of Product, and (iii) establishing and modifying the terms and conditions with respect to the sale of the Product, including any terms and conditions relating to the price (including discounts) at which the Product will be sold.

3.6 **Progress Updates**. At the written request of NewLink (but no more than [*]), Merck will provide to NewLink an update on the progress of its Development activities related to Product.

3.7 **Regulatory Matters**. In the event that Merck determines that any regulatory filings for any Compounds or Products are required for any activities hereunder (including any activities under the Transition Program), including INDs, BLAs and other Marketing Authorizations (as applicable), then as between the Parties, Merck (or its Affiliate or Related Party or other designee) shall have the sole right, in its discretion, to obtain such regulatory filings (in its (or its Affiliate's or its Related Party's or other designee's) name) and as between the Parties, Merck (or its Affiliate or its Related Party or other designee) shall be the owner of all such regulatory filings. As between the Parties, Merck (or its Affiliate or Related Party or other designee) shall have the sole right to communicate and otherwise interact with Regulatory

Authorities with respect to the Compounds and/or Products, including with respect to any INDs, BLAs and other Marketing Authorizations in connection therewith. NewLink (and its Affiliates) shall have no right to, and shall not, make any regulatory filings related to any Compounds or Products or otherwise interact with any Regulatory Authorities with respect to the Compounds or Products; provided that [*] expressly set forth in the NewLink Funding Agreements in accordance with this Agreement [*] and [*], NewLink shall [*]; provided that, in connection with [*], as applicable, NewLink shall [*] with respect thereto (including [*]) and, to the extent not inconsistent with Applicable Law or [*], NewLink shall [*] in connection therewith (and in connection therewith, NewLink [*]). At the request of Merck, NewLink shall use Commercially Reasonable Efforts to assist Merck in communicating with, filing with, or responding to questions of Regulatory Authorities.

3.8 **Excused Performance**. The obligation of Merck with respect to any Product under Section 3.5 is [*] of the [*], and the obligation of Merck to develop or commercialize any such Product [*].

3.9 **No Implied Licenses**. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Confidential Information disclosed to it under this Agreement or under any patents or patent applications owned or Controlled by the other Party or its Affiliates.

3.10 **Third Party Funding**.

3.10.1 **Government Funding Opportunities**. Each Party shall [*] for the Development, Manufacturing or Commercialization of Product of which it becomes aware during the Transition Period. The Parties will [in good faith discuss each such opportunity] and determine [which Party has the capabilities and resources to obtain such funding]. Unless otherwise agreed by the Parties, Merck [shall be given the opportunity (but Merck shall not be obligated) to pursue such funding opportunity (and NewLink shall not pursue any such funding opportunity unless approved by Merck in writing)] and NewLink [shall not be obligated to pursue any funding opportunity (except as expressly set forth in the following proviso) unless it agrees otherwise]; provided that, notwithstanding the foregoing, but subject to Section 3.11, NewLink [*] (the [*], the "**NewLink Future Funding Agreements**" and together with the NewLink Existing Funding Agreements, the "**NewLink Funding Agreements**"). Subject to Section 3.10.2, [*] under this Section 3.10.1 shall [*] with which it [*].

3.10.2 **NewLink Agreements**. NewLink shall be responsible for, and shall control all aspects of, the administration of the NewLink Funding Agreements; provided that [*] with respect to the [*] and [*] with respect to the [*], including to allow [*] under

such [*] that such [*]; provided further, that in no event shall NewLink be required to [*] (provided that, for clarity, if [*] then NewLink shall [*]), or [*] obligations under the NewLink Funding Agreements. In addition, the Parties agree that [*] under a NewLink Funding Agreement (and in such case, [*] to comply with [*]); provided, however, that in the event that either (x) [*] to provide [*], (y) [*], or (z) [*] under the applicable [*] then, in each case, the Parties [*] with respect to, and shall [*] with any [*]. In connection with any [*], NewLink shall [*]; provided that NewLink shall [*] to the extent any [*]. To the extent that [*] that would be [*], NewLink shall [*] to Merck [*], unless the Parties otherwise agree that [*] pursuant to [*], in which case NewLink shall [*].

3.10.3 **Activities and Materials under NewLink Funding Agreements**. NewLink shall be responsible for compliance with the terms of the NewLink Funding Agreements; provided that Merck shall have the rights as set forth in Section 3.10.2. Promptly (and no later than [*] with respect to any material Know-How or other materials and [*] with respect to all other Know-How and materials) after the creation or generation of any Know-How or other materials under any NewLink Funding Agreement, NewLink [*]. NewLink shall ensure ([*]) that Merck has the rights to use, and hereby grants to Merck and its Related Parties the rights to use, such Know-How and materials in accordance with the exercise of the license set forth in Section 3.1 (and for clarity, such Know-How and materials shall be included in the licenses granted under Section 3.1); provided that, to the extent that NewLink [*] in and to any [*], NewLink shall, [*] (the "[*]") (and in such case, such [*] shall not be included in the licenses granted under Section 3.1); provided further that, Merck (and its Related Parties) shall only [*] in connection with the Compounds and Products.

3.10.4 **Merck Agreements**. Merck will use Commercially Reasonable Efforts to establish [*] by the end of the Transition Period. Following the expiration of the Transition Period (or prior to the expiration of the Transition Period, if agreed to by the Parties), at the written request of Merck, NewLink shall [*], and in connection therewith, NewLink shall [*] Merck (or its Affiliate), including [*]; provided that (i) NewLink shall not [*] to the extent any [*] to provide [*] and (ii) NewLink shall not [*] provide any [*] unless such [*].

3.11 **Additional NewLink Third Party Agreements**. NewLink shall [*] after the Effective Date [*] not to be [*]. In connection therewith, (i) NewLink shall [*] and (iii) [*] of any such [*].

ARTICLE 4CONFIDENTIALITY AND PUBLICATION

4.1 **Non-Disclosure and Non-Use Obligation**. All Confidential Information disclosed by one Party to the other Party or its Affiliate hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein, without the prior written consent of the disclosing Party, except to the extent that such Confidential Information:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

(b) is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;

(c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

(d) is independently developed by the receiving Party without access to or reference to Confidential Information received from the disclosing Party, as documented by the receiving Party's business records contemporaneous with such development.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

4.2 **Permitted Disclosures**. Notwithstanding Section 4.1, a receiving Party shall be permitted to disclose Confidential Information of the disclosing Party, if such Confidential Information:

(a) is disclosed to governmental or other regulatory agencies in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product under this Agreement, in each case, in accordance with this Agreement, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations, and provided that reasonable steps are taken to ensure confidential treatment of such Confidential Information (if available);

(b) is disclosed by the receiving Party (or its Affiliates) to Related Parties, agent(s), consultant(s), and/or other Third Parties for any and all purposes the receiving Party or its Affiliates deem necessary or advisable in the course of conducting activities in accordance with this

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Agreement (including the exercise of licenses granted to the receiving Party hereunder, and/or, in the case of Merck (or its Affiliates), engaging in transactions with potential Third Party collaborators, service providers and/or other transferees of rights and/or obligations hereunder) on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, that, with respect to Confidential Information received by NewLink from Public Health Canada, the foregoing shall at all times be subject to terms of confidentiality and non-use provisions of the NewLink Canada License;

(c) is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement;

(d) is deemed necessary by the receiving Party to be disclosed in connection with a potential or actual financing, merger or acquisition of the receiving Party (or its Affiliate), in which case such Party shall have the further right to disclose Confidential Information to Third Parties involved in such financing, merger or acquisition, provided that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; or

(e) is required by the terms of the NewLink Canada License to be disclosed to Public Health Canada to satisfy NewLink's or Merck's, as applicable, obligations to report any required information, on the condition that, Public Health Canada be bound by terms of confidentiality and non-use provisions with respect to such information, as specified in the NewLink Canada License.

In addition, if a Party is required by judicial or administrative process or Applicable Law to disclose Confidential Information of the other Party that is subject to the non-disclosure provisions of Section 4.1, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process or as required by Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of Section 4.1, and the Party disclosing Confidential Information pursuant to law or court order or as required by Applicable Law shall take all steps reasonably necessary, including without limitation obtaining an order of

confidentiality, to ensure the continued confidential treatment of such Confidential Information.

4.3 **Know-How; Joint Know-How**. Without limiting the provisions of Section 4.1, with respect to any [*], subject to Section 4.1.

4.4 **Ownership of Confidential Information**. For the purposes of this Article 4, where pursuant to the terms of this Agreement one Party owns Confidential Information that has been generated by the other Party, then such Confidential Information shall be treated as if it had been generated by such owning Party and disclosed by such owning Party to such other Party.

4.5 **Terms of Agreement.** Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except as follows: A Party and its Affiliates may disclose the terms or conditions of this Agreement (but not any other Confidential Information, which may be disclosed only as described elsewhere in this Article 4), (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary; provided that such advisors are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or are bound by written agreements providing for confidentiality and non-use obligations, in each case, that are no less stringent than those confidentiality and non-use provisions contained in this Agreement; (b) to a Third Party in connection with a potential or actual (i) merger, consolidation or similar transaction by such Party or its Affiliates, (ii) sale of all or substantially all of the assets of such Party or its Affiliates (or, with respect to Merck, sale of all or substantially all of the assets of Merck to which this Agreement relates) or (iii) financing; provided that, in each case, the disclosing Party shall ensure that such Third Party is bound by confidentiality and non-use obligations with respect to Confidential Information of the other Party no less restrictive than those contained in this Agreement and such disclosing Party shall be fully liable to the other Party for breach of the confidentiality and non-use obligations under this Agreement by such Third Parties; (c) to the United States Securities and Exchange Commission or any other securities exchange or governmental authority, including as required to make an initial or subsequent public offering; or (d) as otherwise required by Applicable Law; provided that in the case of (c) and (d) the disclosing Party shall (x) submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [*] prior to the anticipated date of disclosure, unless such shorter period is reasonably necessary to comply with Applicable Law) so as to provide a reasonable opportunity to comment on any such required disclosure, (y) if requested by such other Party, seek, or cooperate with such Party's efforts to obtain, confidential treatment or a protective order with respect to any such disclosure to the extent

available at such other Party's expense, and (z) use good faith efforts to incorporate the comments of such other Party in any such disclosure or request for confidential treatment or protective order, and if disclosure of the terms of this Agreement is required by Applicable Law or the rules of any securities exchange or market on which a Party's securities are listed or traded, the Parties shall agree on a redacted version of this Agreement to be so disclosed; provided, however, that in the event the Parties cannot agree on such a redacted version of the Agreement, the disclosing Party shall have the right to disclose such terms of this Agreement as such Party's counsel determines is necessary to comply with Applicable Law or the rules of any securities exchange or market on which such Party's securities are listed or traded.

4.6 **Publicity/ Use of Names; Press Releases**.

4.6.1 **General**. The Parties have mutually agreed on the press release with respect to this Agreement, a copy of which is set forth in Schedule 4.6. Either Party may make subsequent public disclosures that are limited to the specific contents of such press release. Except as otherwise expressly set forth herein, no disclosure of the terms of this Agreement may be made by either Party (or its respective Affiliates), and no Party (or its respective Affiliates) shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law, including the rules of any securities exchange or market on which a Party's securities are listed or traded; provided that in the event disclosure is required by Applicable Law, the disclosing Party shall use good-faith efforts to give the non-disclosing Party an opportunity, with reasonable advance notice, as practicable under the circumstances, to review and comment on any proposed disclosure.

4.6.2 **NewLink Publicity**. NewLink shall not issues any other press release or public announcement related to the Transition Program and/or any Compound or Product without the prior written approval of Merck; provided that if (i) such press release or public announcement is required by Applicable Law or (ii) the failure to issue such press release or public announcement would cause NewLink to breach a NewLink Funding Agreement, then NewLink may issue such press release or public announcement; provided that NewLink shall provide a copy thereof to Merck at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [(] notice). Merck shall be allowed to review and comment on such proposed publication and

NewLink shall reasonably consider any comments provided by Merck with respect thereto in a timely fashion.

4.6.3 **Merck Publicity**. During the Transition Period, Merck may not issue any other press release or public announcement relating to the Transition Program and/or any Compound or Product, without providing NewLink a copy of such proposed press release or public announcement at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [*] notice), and in connection therewith, NewLink shall be allowed to review and comment on such proposed publication and Merck shall reasonably consider any comments provided by NewLink with respect thereto in a timely fashion. Following the Transition Period, Merck may issue any press release or public announcement relating to the Transition Program and/or any Compound or Product; provided that, to the extent practicable, Merck shall notify NewLink thereof at least [*] prior to the proposed publication thereof (or with as much advance notice as possible under the circumstances if it is not possible to provide at least [*] notice).

4.7 **Publications**. NewLink shall publish scientific information related to the Compounds or Products (including the results of the Transition Program), only with the prior written consent of Merck]; provided that if [*], then NewLink may make such publication; provided that NewLink shall [*] on any [*] and [*]. Merck shall have the right to publish information related to the Compounds and Products (including the results of the Transition Program) [*].

4.8 **Clinical Trial Registration**. Notwithstanding the foregoing, in all cases, Merck shall have the right to register clinical trials and publish the results or summaries of results of any clinical trials conducted hereunder with respect to Compound or Product on clinicaltrials.gov or other similar registry.

4.9 **Remedies**. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 4.

4.10 **Prior Non-Disclosure Agreements**. As of the Effective Date, the terms of this Article 4 shall supersede (i) the Existing Confidentiality Agreement and (ii) the Tri-Party Confidentiality Agreement (but solely to the extent that the Tri-Party Confidentiality Agreement applies as between Merck on the one hand, and NewLink and NL, on the other hand), and, this Article 4 shall apply to any confidential information disclosed by a Party

(or its Affiliate) under either the Existing Confidentiality Agreement or the Tri-Party Confidentiality Agreement, as applicable.

ARTICLE 5PAYMENTS AND REPORTS

5.1 **Upfront Payment**. In consideration of the license and other rights granted to Merck herein, Merck shall pay to NewLink, within [*] following the Effective Date, a one-time, non-refundable upfront payment in the amount of Thirty Million Dollars ($30,000,000).

5.2 **Milestone Payment**. Subject to the terms and conditions of this Agreement, Merck shall pay to NewLink a one-time, non-refundable payment in the amount of Twenty Million Dollars ($20,000,000) (the "**Milestone Payment**") within [*] following [*] as [*] (the "**Milestone Event**").

5.3 **[*]**.

5.3.1**[*]**. If, at any time during the Term, [*] Merck or a Related Party [*] or to [*] (the "[*]"), [*] shall promptly notify the other Party thereof. If Merck or a Related Party [*], then, upon [*], to the extent legally permissible, Merck (or such Related Party, as applicable) shall [*], and in connection therewith, the Parties [*] of such [*]. In all cases (whether [*] was received by [*] or [*] of its intent to [*], then [*] in the [*] plus [*] in connection with [*] in connection with [*], and [*] a Third Party, then [*], and [*] not to [*], and [*] of any and all [*] in connection with [*] by Merck (or its Related Party) solely in connection with [*]. For clarity, the provisions of this Section 5.3 shall only apply with respect to [*], and [*]. As used in this Section 5.3.1, the term "[*]" shall mean [*], which shall be mutually agreed to by the Parties [*]; provided that if [*], then [*] to each of the Parties.

5.3.2**[*]**. If, at any time during the Term, [*] Merck or a Related Party [*] or to [*] (the "[*]"), [*] shall promptly notify the other Party thereof. If Merck or a Related Party [*], then, upon [*], to the extent legally permissible, Merck (or such Related Party, as applicable) shall [*], and in connection therewith, the Parties [*]. In all cases (whether [*] was received by [*] or [*] of its intent to [*], then [*] in the [*] plus [*] in connection with [*] in connection with [*], and [*] to a Third Party, then [*], and [*] not to [*], and [*] of any and all [*] in connection with [*] by Merck (or its Related Party) solely in connection with [*]. For clarity, the provisions of this Section 5.3 shall only apply with respect to [*], and [*]. As used in this Section 5.3.1, the term "[*]" shall mean [*], which shall be mutually agreed to by the Parties [*]; provided that if [*], then [*] to each of the Parties.

5.3.3 **Obligation to [*]**. Merck shall, upon NewLink's reasonable request [*], undertake [*] to [*] or [*] that may be available to [*].

5.3.4 **Tax Matters**. Upon the issuance of [*] or [*], the Parties shall discuss in good faith [*] under this Section 5.3.4 [*].

5.4 **Royalty Payments**.

5.4.1 **Royalty Rates.** Subject to the other terms of this Section 5.4, on a Product-by-Product basis, during the Royalty Term for a given Product in a given country in the Royalty Bearing Territory, Merck shall make, on a Calendar Year basis, royalty payments to NewLink on the Product Net Sales of such Product in a given Calendar Year in such countries at the applicable royalty rate set forth below (which royalty rates shall be different for the Current Product and for any other Product as set forth below). For clarity, the royalties (and royalty tiers) shall be calculated separately on a Product-by-Product basis.

Current Product	
Annual Product Net Sales of a given Product in the Royalty-Bearing Territory in a given Calendar Year	**Royalty Rate for Product Net Sales**
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory up to and including $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] and less than or equal to $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] and less than or equal to $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] in a given Calendar Year	[*]%
Products other than Current Product	

Annual Product Net Sales of a given Product in the Royalty-Bearing Territory in a given Calendar Year	Royalty Rate for Product Net Sales
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory up to and including $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] and less than or equal to $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] and less than or equal to $[*] in a given Calendar Year	[*]%
Portion of annual Product Net Sales for a given Product in the applicable countries in the Royalty Bearing Territory greater than $[*] in a given Calendar Year	[*]%

For clarity, (i) if no royalty is payable on a given unit of Product (e.g., following the Royalty Term for such Product in a given country or sales of a given Product outside of the Royalty Bearing Territory), then the Product Net Sales of such unit of Product shall not be included for purposes of determining the foregoing royalty tiers and (ii) Product Net Sales of a given Product will not be combined with Product Net Sales of any other Product for purposes of determining the foregoing royalty tiers.

5.4.2**Royalty Term**. Merck's royalty payment obligations under this Agreement with respect to a given Product shall commence upon [*] in the Field anywhere in the Royalty Bearing Territory by Merck or Related Parties, and shall continue, (i) with respect to the [*] Product, on a Product-by-Product basis, until [*] expiration of the last to expire Valid Claim included in NewLink Patent Rights [*] that Covers such Product, and (ii) with respect to [*], on a Product-by-Product and country-by-country basis, until the later of (x) the expiration of the last to expire Valid Claim included in NewLink Patent Rights in the country of sale that Covers such Product in such country or (y) [*] after the [*] of such Product in such country (the "**Royalty Term**").

5.4.3**Royalty Reduction**.

(c) **Know-How Royalty**. Subject to Section 5.4.3(c) below, if a Product is generating Product Net Sales in a country in the Royalty Bearing Territory during the Royalty Term at a time when there is no Valid Claim (i) with respect to the [*] Product, included in the NewLink Patent Rights [*] that Covers such Product, [* (ii) with respect to [*]than the [*] Product, included within the NewLink Patent Rights in such country that Covers such Product in such country, then the royalty rate applicable to Product Net Sales of such Product in such country in the Royalty Bearing Territory pursuant to Section 5.4.1 thereafter shall be reduced by [*].

(d) **Reduction for Third Party Payments**. Subject to Section 5.4.3(c) and 5.4.3(d) below, Merck or any Related Party obtains a right or license under any intellectual property of a Third Party (whether prior to, or after, the Effective Date), where the research, development, making, using, selling, offering for sale, or importing of Product (or Compound contained in such Product) by Merck or any Related Party would result in a payment to such Third Party, then Merck may deduct from the royalty payment that would otherwise have been due under this Section 5.4 with respect to Product Net Sales of such Product in a particular Calendar Quarter, an amount equal to [*] pursuant to such right or license in connection with the research, development, making, using, selling, offering for sale, or importing of Product (or Compound contained therein) during such Calendar Quarter; provided, however, that in no event shall the royalties payable on Product Net Sales of Product be reduced by more than [*] in any Calendar Quarter by operation of this Section 5.4.3(b) (provided, however, that [*] as a result of [*] shall be [*] with respect to such [*]).

(e) **Payments to Public Health Canada by Merck**. Notwithstanding anything to the contrary contained herein, in the event that Merck (or its Related Party, as applicable) pays any royalties or other amounts directly to Public Health Canada in connection with any Compound or Product (or the research, development, making, using, selling, offering for sale, or importing thereof), then (i) [*], and [*] and (ii) to the extent that Merck [*] from the [*] to NewLink in a [*], then NewLink [*] for the [*].

(f) **Minimum Royalty Rate**. Notwithstanding the foregoing provisions of this Section 5.4.3 (but subject to Section 5.4.3(c) and 5.4.6), for so long as NewLink [*] as a result of sales of Product by Merck or its Related Parties in the Royalty Bearing Territory hereunder, in no event shall the royalty rate payable by Merck under this Section 5.4 due on Product Net Sales hereunder be reduced pursuant to the foregoing provisions of this Section 5.4.3 to less than [*], including [*]; provided that, for clarity, the provisions of this Section 5.4.3(d) are not intended to, and shall not be interpreted to, expand Merck's royalty obligations hereunder

(other than with respect to the royalty rate payable by Merck as expressly set forth in this Section 5.4.3(d)), including [*].

5.4.4**Change in Sales Practices**. The Parties acknowledge that during the term of this Agreement, Merck's sales practices for [*] to the extent [*] may become [*]. In such event, at the request of Merck, the Parties [*] to the extent currently contemplated under this Section 5.4.

5.4.5**Royalties for Bulk Compound**. In those cases in which Merck (or its Related Party) sells bulk Compound rather than Product in packaged form to an independent Third Party, the royalty obligations of this Section 5.4 shall be applicable to the bulk Compound only (but solely to the extent that a royalty would otherwise by payable on the Product incorporating such Compound).

5.4.6**[*]**. If [*] with respect to Product in any country in the Royalty Bearing Territory [*], then the [*] in such country [*] shall be [*] and in such case, [*]; provided that if as a result of this Section 5.4.6, the royalty rate on Product Net Sales of such Product in such country [*] (or [*], including taking into account [*]), then for so long as [*] pursuant to the [*] hereunder in such country in the Royalty Bearing Territory (and provided that [*] is still in effect with respect to [*]), then the Parties [*] between the [*] on such [*] and the [*] with respect to [*] in such country.

5.4.7**Additional Conditions**. All royalties are subject to the following conditions:

(a) that only one royalty shall be due with respect to the same unit of Product; and

(b) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck's or its Related Party's Product Net Sales to the first independent Third Party; and

(c) the determination of whether a royalty will be calculated and payable hereunder shall be determined on a Product-by-Product basis.

5.4.8**Royalty Reports and Payments**. Within [*] after each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Product is made anywhere in the Royalty Bearing Territory, Merck shall provide NewLink with a report that contains the following information for the applicable Calendar Quarter, on a Product-by-Product and country-by-country basis for the Royalty Bearing Territory: (i) the amount of gross sales of the Products, (ii) a reconciliation between gross sales and Product Net Sales, as specified in the definition thereof, and (iii) a calculation of the royalty payment due on such sales,

including any royalty reduction made in accordance with this Section 5.4. Concurrent with the delivery of the applicable quarterly report, Merck shall pay in Dollars all royalties due to NewLink with respect to Product Net Sales by Merck and its Related Parties for such Calendar Quarter.

5.4.9 **Currency Exchange**. All payments to be made by a Party under this Agreement shall be made in Dollars, by wire transfer, pursuant to the instructions of the Party receiving payment, as designated from time to time. The wire instructions for NewLink are set forth on Schedule 5.4.9 (which instructions may be updated in writing by NewLink to Merck). For purposes of calculating the net royalty obligation, to the extent Product is sold in a currency other than Dollars, the amount received shall be converted into Dollars on a monthly basis using as a rate of exchange [*].

5.5 **Records and Audits**.

5.5.1 Merck shall (and shall cause its Affiliates to) maintain complete and accurate records in sufficient detail to permit NewLink to confirm the accuracy of the royalty payments under this Agreement. Upon reasonable prior notice, such records shall be open during regular business hours for a period of [*] from the creation of individual records for examination by an independent international certified public accountant selected by NewLink and reasonably acceptable to Merck for the sole purpose of verifying for NewLink the accuracy of the royalty reports furnished by Merck pursuant to this Agreement or of any royalty payments made, or required to be made by Merck pursuant to this Agreement. Such audits shall not occur more often than [*] each Calendar Year. Such auditor shall not disclose Merck's Confidential Information to NewLink, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Merck or the amount of payments by Merck under this Agreement. If the accountant correctly identifies a discrepancy, any amounts shown to be owed but unpaid (or overpaid, as applicable) shall be paid by the applicable Party within [*] after the accountant's report. NewLink shall bear the full cost of such audit unless such audit reveals an underpayment by Merck that resulted from a discrepancy in the financial report provided by Merck for the audited period, which underpayment was more than [*], in which case Merck shall reimburse NewLink for the fees of the accountant for such audit.

5.5.2 Upon the expiration of [*] following the end of any Calendar Year, the calculation royalties payable with respect to such Calendar Year shall be binding and conclusive

upon NewLink, and Merck (and its Affiliates) shall be released from any liability or accountability with respect to such royalties for such Calendar Year.

5.5.3 NewLink shall treat all financial information subject to review under this Section 5.5 in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Merck and/or its Affiliates obligating it to retain all such Confidential Information in confidence pursuant to such confidentiality agreement.

5.6 **Taxes**.

5.6.1 **Generally**. Each Party will pay any and all taxes levied on account of all payments it receives under this Agreement except as otherwise provided in this Section 5.7.

5.6.2 **Transfer Taxes**. [*] shall be liable for all transfer taxes (including value added tax (VAT), Canadian Goods and Services taxes (GST), sales and use tax, and other similar taxes), including interest ("**Transfer Taxes**") imposed upon any [*] under this Agreement, including this Article 5. The Parties shall reasonably cooperate in accordance with Applicable Laws to (i) minimize Transfer Taxes payable in connection with this Agreement and (ii) ensure all tax returns relating to Transfer Taxes are properly filed.

5.6.3 **Income Tax Withholding**. If Applicable Laws require that taxes be withheld with respect to any payments by under this Agreement, the payor will: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to the payee on a timely basis following that tax payment. Each Party agrees to reasonably cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with Applicable Laws.

5.7 **NewLink Third Party Agreements**. Notwithstanding anything to the contrary herein, [*], NewLink shall be solely responsible for (and [*] to the extent [*]) all costs and payments of any kind (including all upfront fees, annual payments, milestone payments and royalty payments) arising under any NewLink Third Party Agreements in connection with the Development, Manufacture, Commercialization or other exploitation of Compounds and/or Products hereunder.

ARTICLE 6REPRESENTATIONS AND WARRANTIES

6.1 **Representations And Warranties Of Each Party**. Each Party represents and warrants to the other Party that as of the Effective Date:

6.1.1such Party is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate power and authority to enter into this Agreement and to perform its obligations hereunder;

6.1.2the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement has been duly executed by such Party. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and

6.1.3the execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not (i) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any governmental authority to which such Party is subject, (ii) violate any provision of the corporate charter, by-laws or other organizational documents of such Party, or (iii) constitute a violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party may be subject although not a party.

6.2 **Additional NewLink Representations and Warranties**. NewLink represents and warrants to Merck that as of the Effective Date:

6.2.1NewLink and NL each has the full right, power and authority to enter into this Agreement, to perform the activities hereunder (including the Transition Program) and to grant the license set forth in Section 3.1.1 and Section 3.2;

6.2.2there are no claims, judgments or settlements against or owed by NewLink (or any of its Affiliates) and no pending or, to NewLink's knowledge, threatened claims or litigation, in each case, relating to the NewLink Patent Rights and/or NewLink Know-How and/or Compounds and/or Products;

6.2.3 Schedule 1.79 sets forth a true, correct and complete list of NewLink Patent Rights existing as of the Effective Date and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. The NewLink Patent Rights and NewLink Know-How constitute [*], the Compounds and/or Products or the Development, Manufacture, Commercialization and/or use thereof, or the performance of the Transition Program;

6.2.4 all issued patents within the NewLink Patent Rights are in full force and effect, and, [*], in whole or in part;

6.2.5 it (and its Affiliates) has not prior to the Effective Date (i) assigned, transferred, conveyed or otherwise encumbered its right, title and/or interest in NewLink Patent Rights or NewLink Know-How, or (ii) otherwise granted any rights to any Third Parties that would, in the case of clauses (i) and/or (ii), conflict with the rights granted to Merck hereunder;

6.2.6 to NewLink's knowledge, [*];

6.2.7 it [*] the NewLink Patent Rights and NewLink Know-How, all of which are, as at the Effective Date, [*];

6.2.8 neither it nor any of its Affiliates has received any written notification from a Third Party that the research, development, manufacture, use, sale or import of Compounds or Products infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party, and NewLink has no knowledge that a Third Party has any basis for any such claim;

6.2.9 NewLink has [*] regarding [*], including [*], and [*];

6.2.10 NewLink has [*] related to NewLink Patent Rights or NewLink Know-How licensed under this Agreement;

6.2.11 NewLink has [*] Compound and/or Product [*] from any [*] or any [*] in any [*], or any other [*] to NewLink or any of the Affiliates [*], or [*] subject of any [*], in each case, with respect to [*] related to the [*];

6.2.12 other than [*] or any other [*] for any Compounds or Products, and, to the best of NewLink's knowledge, [*] for any Compounds or Products. The [*] and neither NewLink nor any of its Affiliates [*];

6.2.13 NewLink has obtained all necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by it as of the

Effective Date, as applicable, in connection with the execution, delivery and performance of this Agreement;

6.2.14 NewLink (and its Affiliates) has not employed or otherwise used in any capacity, and will not (during the Transition Program) employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment or debarred under United States law, including under 21 USC 335a or any foreign equivalent thereof, with respect to the Compounds or Products or otherwise in performing any portion of the Transition Program (or any portion of the NewLink Funding Agreements);

6.2.15 all [*] related to the Compounds and/or Products [*] and, to NewLink's knowledge, all [*] related to the Compounds and/or Products [*] in accordance with all Applicable Laws;

6.2.16 all information and data provided by or on behalf of NewLink to Merck on or before the Effective Date in contemplation of this Agreement was and is true and accurate and complete in all material respects, and NewLink has not disclosed, failed to disclose, or cause to be disclosed, any material information or data that would reasonably be expected to cause the information and data that has been disclosed to be misleading in any material respect;

6.2.17 it [*];

6.2.18 other than [*], there are no [*] or other [*] the NewLink Know-How or NewLink Patent Rights;

6.2.19 with respect to each NewLink Existing Third Party Agreement and each NewLink Future Funding Agreement [*] it is in full force and effect; [*] to such [*] or [*] from the [*] any of the [*], and [*] which could [*] the scope of [*] any of the [*]; and [*] relating to any [* or any other [*];

6.2.20 the [*] provided to Merck [*] in accordance with [*]. Such [*] is not [*] and is not [*], under the [*]. All such [*];

6.2.21 Schedule 6.2.21 sets forth [*] by NewLink to be [*] (the "**Product Materials**");

6.2.22 Other than the [*], neither NewLink nor any of its Affiliates has [*], and with respect to the [*], NewLink has [*] under the [*];

6.2.23 Except with respect to [*], neither NewLink nor its Affiliates [*] for the [*], in each case, other than with respect to the Current Compound and Current Product;

6.2.24 No Know-How or other intellectual property within the NewLink Know-How or NewLink Patent Rights [*];

6.2.25 Except with respect to the rights expressly retained by Public Health Canada under the NewLink Canada License, [*] Know-How, Patent Rights or other intellectual property [*], and, except with respect to the rights expressly retained by Public Health Canada under the NewLink Canada License [*] to any such [*]; and

6.2.26 NewLink is a wholly-owned subsidiary of NL, and, except as set forth on Schedule 6.2.26, there are no other Affiliates of either NewLink or NL.

6.3 **Additional Merck Representations and Warranties**.

6.3.1 Merck represents and warrants to NewLink that as of the Effective Date, Merck has determined pursuant to 16 C.F.R. Sec. 801.10 that no filing is required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended and the rules promulgated thereunder, with respect to the subject matter of this Agreement.

6.4 **Warranty Disclaimer**. EACH PARTY HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREIN NOT EXPRESSLY MADE IN THIS AGREEMENT TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAWS, INCLUDING WITH RESPECT TO THE COMPOUNDS, PRODUCTS, OR ANY TECHNOLOGY OR OTHER INTELLECTUAL PROPERTY LICENSED OR GRANTED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT, QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS SECTION 6.4 SHALL OPERATE TO LIMIT OR INVALIDATE ANY EXPRESS REPRESENTATION OR WARRANTY CONTAINED HEREIN.

6.5 **NewLink Third Party Agreements**. NewLink represents and warrants to Merck that [*] and [*], and [*] as of the Effective Date. NewLink [*] (a) [*] in full force and effect, [*]; (b) [*] has been [*] any of the [*]; (c) [*] of any [*] any of the [*] or [*], made by [*] and (d) to the extent [*], it shall promptly [*] of all other [*] to such [*] related to such [*].

6.6 **[*]**. During the period from the Effective Date until [*], each Party agrees and covenants to [*] or the Parties [*]; provided, however, that [*] such Party [*]. A violation of [*] may be [*].

ARTICLE 7INTELLECTUAL PROPERTY

7.1 **Ownership of Background Technology**. As between the Parties, any NewLink Know-How existing prior to the Effective Date and owned by NewLink shall, during the Term and upon expiration or termination of this Agreement, continue to be owned exclusively by NewLink. As between the Parties, any Merck Know-How shall, during the Term and upon expiration or termination of this Agreement, continue to be owned exclusively by Merck.

7.2 **Program Know-How**.

7.2.1 **Ownership**. For purposes of determining ownership under this Section 7.2.1, inventorship of Program Know-How and Program Patent Rights shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Notwithstanding the foregoing, all right, title and interest in any Program Know-How and Program Patent Rights, in each case, shall be determined in accordance with the following terms and conditions:

(a) As between the Parties, NewLink shall own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice solely by one or more employees, agents or consultants of NewLink, its Affiliates, or its subcontractors (but excluding Merck (or its Affiliates) as a subcontractor of NewLink under any NewLink Funding Agreement) (such Program Know-How, the "**NewLink Program Know-How**" and such Program Patent Rights, the "**NewLink Program Patent Rights**");

(b) As between the Parties, Merck shall own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice solely by one or more employees, agents or consultants of Merck, its Affiliates, or its subcontractors (such Program Know-How, the "**Merck Program Know-How**" and such Program Patent Rights, the "**Merck Program Patent Rights**"); and

(c) NewLink and Merck shall jointly own all right, title and interest in any Program Know-How (and Program Patent Rights that claim or cover such Program Know-How) that is conceived, discovered or reduced to practice by one or more employees, agents or consultants of NewLink, its Affiliates, or its subcontractors, together with one or more employees, agents or consultants of Merck, its Affiliates, or its subcontractors (such Program Know-How, the "**Joint Program Know-How**" and such Program Patent Rights, the "**Joint Program Patent Rights**"). Subject to the licenses granted to the other Party under this Agreement and the other terms of this Agreement, each Party has a right to exploit its interest in such Joint

Program Know-How and Joint Program Patent Rights without the consent of, and without accounting to, the other Party; provided, however, that for clarity, the foregoing joint ownership rights with respect to Joint Program Know-How and Joint Program Patent Rights shall not be construed as granting, conveying or creating any license or other rights to the other Party's intellectual property, unless otherwise expressly set forth in this Agreement.

7.2.2 **Assignment of Interests to Effectuate Ownership of Joint Program Know-How and Joint Program Patent Rights**. With respect to any Joint Program Know-How and Joint Program Patent Rights, each of NewLink and Merck shall on behalf of itself and each of their respective Affiliates, employees and contractors hereunder, assign to one another (without payment of additional consideration), in perpetuity throughout the world, ownership of an undivided interest in and to such Program Know-How and Program Patent Rights if necessary to effect the ownership of such Program Know-How and Program Patent Rights as set forth in Section 7.2.1(c), subject to any licenses expressly granted under this Agreement. In furtherance of the foregoing, each Party shall, upon request by the other, promptly undertake and perform (and/or cause its Affiliates and its and their respect employees and/or agents to promptly undertake and perform) such further actions as are reasonably necessary for NewLink and Merck to, as between the Parties, perfect its title in any such Program Know-How and Program Patent Rights as set forth in Section 7.2.1(c), as, and to the extent, applicable, including by causing the execution of any assignments or other legal documentation, and/or providing the other Party or its patent counsel with reasonable access to any employees or agents who may be inventors of such Program Know-How and Program Patent Rights.

7.3 **Filing, Prosecution and Maintenance of Patent Rights**.

7.3.1 **Joint Program Patent Rights and NewLink Patent Rights**.

(a) Joint Program Patent Rights and NewLink Patent Rights. With respect to any Joint Program Patent Rights and any NewLink Patent Rights, [*] shall have the first right (in its discretion), at its cost, to Prosecute such Patent Rights in the name of both Parties (with respect to Joint Program Patent Rights) or NewLink (with respect to NewLink Patent Rights); provided, however, that [*] shall only have the right to Prosecute [*] and [*] to the extent such Prosecution [*]. In connection therewith, [*] as may be [*] the Joint Program Patent Rights and NewLink Patent Rights. [*] may elect to use outside counsel for such Prosecution. With respect to a given Joint Program Patent Right or NewLink Patent Right, [*] (i) may elect not to Prosecute, (ii) may elect not to Prosecute in a particular country (including electing not to validate in a particular country) and/or (iii) may elect to discontinue Prosecution in a particular country; and in case of clause (ii) or clause (iii), [*] shall provide

[*] with notice thereof (provided that with respect to the foregoing clause (iii), such notice shall be provided in a timely manner) and [*] shall have the right (but not the obligation), at its sole expense and upon written notice to [*], to assume such responsibility for the Prosecution of such Joint Program Patent Right (in the name of both Parties) or NewLink Patent Rights (in the name of NewLink) to the extent [*] has elected not to do so; provided, however, that if [*] elects to [*] in the [*] in such [*], then, in the event that [*] thereafter [*], and the [*] in such country under such [*], then [*] shall [*] incurred by [*] in such country [*]. [*] shall comply with all applicable obligations (but [*]) under [*] applicable to the Prosecution of [*] by [*] and [*].

(b) Review and Consultation. With respect to the Joint Program Patent Rights and NewLink Patent Rights, upon the written request of the non-Prosecuting Party, the Prosecuting Party shall give the non-Prosecuting Party an opportunity to review the text of any application before filing, shall consult with the non-Prosecuting Party with respect thereto (and shall consider the non-Prosecuting Party's comments thereto in good faith), and shall supply the non-Prosecuting Party with a copy of the application as filed, together with notice of its filing date and serial number. Upon request of the non- Prosecuting Party, the Prosecuting Party shall keep the other Party advised of the status of such actual and prospective patent filings and, upon such other Party's request, shall provide advance copies of any material papers to be filed related to the filing, prosecution and maintenance of such patent filings. Each Party shall promptly give notice to the other Party of the grant, lapse, revocation, surrender, invalidation or abandonment of such Joint Program Patent Rights or NewLink Patent Rights for which it is responsible for the filing, prosecution and maintenance.

7.3.2**Merck Patent Rights**. Merck shall have the sole right, in its discretion and at its own expense, to Prosecute the Merck Patent Rights, and NewLink shall have no rights in connection therewith.

7.3.3**Cooperation**. As requested by the Prosecuting Party, the non-Prosecuting Party shall provide the Prosecuting Party with reasonable assistance in connection with the Prosecution of Patent Rights under this Section 7.3, including (i) giving the Prosecuting Party reasonable access to its employees, agents, consultants and subcontractors and those of the non-Prosecuting Party's Affiliates for the purposes of identifying inventors of subject matter in any such Patent Rights, and (ii) obtaining any necessary declarations and assignments from its named inventors or those under obligation to assign inventions hereunder, and providing relevant technical reports (including, if necessary, laboratory notebooks), to the Prosecuting Party concerning the subject invention. Without limiting the foregoing, if a power of attorney from the non-Prosecuting Party is needed to facilitate the Prosecuting Party's Prosecution

of Patent Rights in accordance with this Section 7.3, the non-Prosecuting Party shall obtain and provide to the Prosecuting Party such power of attorney.

7.3.4 **Prosecution Matters**. For the avoidance of doubt, all interferences, oppositions, appeals or petitions to any board of appeals in any patent office, appeals to any court for any patent office decisions, reissue proceedings, invalidation proceedings, re-examination proceedings, *inter partes* reviews, post grant reviews, derivation proceedings or other similar administrative proceedings or administrative appeals thereof, with respect to any Patent Rights under this Agreement shall be considered patent Prosecution matters, and shall be handled in accordance with this Section 7.3. With respect thereto, the non-Prosecuting Party shall (i) join (if required to bring such action) such action voluntarily, and (ii) execute and cause its Affiliates to execute all documents necessary for the Prosecuting Party to initiate such action in the event that the Prosecuting Party is unable to initiate or prosecute such action solely in its own name. In all cases, with respect to the Prosecution of the NewLink Patent Rights or Joint Program Patent Rights, as applicable, the Prosecuting Party shall not enter into any settlement that would oblige the non-Prosecuting Party (or any of its Related Parties) to make any payment or would have a detrimental effect on the Compounds or Products, or the rights or licenses of the non-Prosecuting Party hereunder, without the non-Prosecuting Party's prior written consent (not to be unreasonably withheld).

7.4 **Enforcement of Patent Rights**.

7.4.1 **NewLink Patent Rights and Joint Program Patent Rights**. NewLink shall give Merck prompt written notice of either (i) any infringement of NewLink Patent Rights or Joint Program Patent Rights and/or (ii) any misappropriation or misuse of NewLink Know-How or Joint Program Know-How that may come to NewLink's attention. Merck and NewLink shall thereafter consult and cooperate fully to determine a course of action, including the commencement of legal action by either or both Merck and NewLink, to terminate any infringement of NewLink Patent Rights or Joint Program Patent Rights or any misappropriation or misuse of NewLink Know-How or Joint Program Know-How, as applicable. However, subject at all times to any applicable terms and conditions of the NewLink Canada License with respect to NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License, Merck, upon notice to NewLink, shall have the first right to initiate and prosecute such legal action at its own expense (including, in the name of NewLink, if necessary) or to control the defense of any declaratory judgment action relating to NewLink Patent Rights, Joint Program Patent Rights, NewLink Know-How or Joint Program Know-How, as

applicable. If NewLink is required to join in such action in order for Merck to bring such action, then, at the reasonable request of Merck, NewLink shall join such action. Merck shall promptly inform NewLink if it elects not to exercise such first right and NewLink shall thereafter have the right (in its discretion) to initiate and prosecute such action (or to control the defense of such declaratory judgment action, as applicable), at its own expense; provided, however, that in all cases, NewLink shall not enter into any settlement that would oblige Merck to make any payment or would have a detrimental effect on the Compounds or Products, or the rights or licenses of Merck hereunder, without Merck's prior written consent. Each Party shall have the right to be represented by counsel of its own choice. For clarity, NewLink shall not bring any action to enforce any NewLink Patent Rights or NewLink Know-How or Joint Program Patent Rights or Joint Program Know-How, as applicable, unless (i) Merck has elected not to exercise its first right as set forth in this Section 7.4.1 or (ii) Merck otherwise consents thereto in writing (in Merck's sole discretion), and in all cases, NewLink shall not agree to any settlement in connection therewith without the prior written consent of Merck (in Merck's sole discretion). Merck shall comply with all obligations (other than [*]) under the NewLink Canada License applicable to the enforcement of the NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License.

7.4.2 **Cooperation**. For any action to terminate any infringement of NewLink Patent Rights or Joint Program Patent Rights, or any misappropriation or misuse of NewLink Know-How or Joint Program Know-How, in the event that Merck is unable to initiate or prosecute such action solely in its own name, NewLink shall join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action by Merck, NewLink shall cooperate fully with Merck and NewLink shall provide Merck with any information or assistance that Merck may reasonably request.

7.4.3 **Information**. In connection with the foregoing, each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

7.4.4 **Recoveries**. Subject at all times to any applicable recovery terms of the NewLink Canada License with respect to enforcement actions of the NewLink Patent Rights that are owned by Public Health Canada and licensed to NewLink under the NewLink Canada License, any recovery obtained by either or both Merck and NewLink in

connection with or as a result of any action contemplated by the foregoing provisions of Section 7.4.1, whether by settlement or otherwise, shall be shared in order as follows:

(a) the Party which initiated and prosecuted the action shall recoup all of its costs and expenses incurred in connection with the action;

(b) the other Party shall then, to the extent possible, recover its costs and expenses incurred in connection with the action; and

(c) the amount of any recovery remaining shall [*].

7.4.5**Biosimilar Applications**.

(a) Notwithstanding the foregoing provisions of this Section 7.4, if either Party receives a copy of a Biosimilar Application referencing a Product or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for marketing authorization (such as in an instance described in 42 U.S.C. §262(l)(9)(C), the remainder of this Section 7.4.5 shall apply. Such Party shall within [*] notify the other Party. The owner of the relevant patents shall then seek permission to view the application and related confidential information from the filer of the Biosimilar Application if necessary under 42 U.S.C. §262(l)(1)(B)(iii). If either Party receives any equivalent or similar communication or notice in the United States or any other jurisdiction, either Party shall within [*] notify and provide the other Party copies of such communication to the extent permitted by Applicable Laws. Regardless of the Party that is the "reference product sponsor," as defined in 42 U.S.C. §262(l)(1)(A), for purposes of such Biosimilar Application:

(i) Merck shall designate, to the extent permitted by law, or otherwise NewLink shall designate in accordance with Merck's instructions, the outside counsel and in-house counsel who shall receive confidential access to the Biosimilar Application pursuant to 42 U.S.C. §262(l)(1)(B)(ii).

(ii) Merck shall have the right, after consulting with NewLink, to list any patents, including those within the NewLink Patent Rights, as required pursuant to 42 U.S.C. §262(l)(3)(A) or 42 U.S.C. §262(l)(7), to respond to any communications with respect to such lists from the filer of the Biosimilar Application, to negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange other than that specified in 42 U.S.C. §262(l)(1) and as to the patents that will be subject to the initial litigation procedure as described in 42 U.S.C. §262(l)(4), to decide which patent or patents shall be selected for initial litigation under 42 U.S.C. §262(l)(5)(B)(i)(II), and to commence

such litigation under 42 U.S.C. §262(l)(6). If required pursuant to Applicable Law, upon Merck's request, NewLink shall execute these tasks after consulting with Merck.

(iii) Merck shall have the right, after consulting with NewLink, to identify patents, including those within the NewLink Patent Rights, or respond to relevant communications under any equivalent or similar listing to those described in the preceding clause (ii) in any other jurisdiction outside of the United States. If required pursuant to Applicable Law, upon Merck's request, NewLink shall assist in the preparation of such list and make such response after consulting with Merck.

(iv) NewLink shall cooperate with Merck's reasonable requests in connection with the foregoing activities to the extent required or permitted by Applicable Laws. Merck shall consult with NewLink prior to identifying any NewLink Patent Rights to a Third Party as contemplated by this Section 7.4.5. Merck shall consider in good faith advice and suggestions with respect thereto received from NewLink, and notify NewLink of any such lists or communications promptly after they are made.

(v) Each Party shall within [*] after receiving any notice of commercial marketing provided by the filer of a Biosimilar Application pursuant to 42 U.S.C. §262(l)(8)(A), notify the other Party. To the extent permitted by law, Merck shall have the first right, but not the obligation, to seek an injunction against such commercial marketing as permitted pursuant to 42 U.S.C. §262(l)(8)(B) and to file an action for infringement. If required pursuant to Applicable Law, upon Merck's request, NewLink shall assist in seeking such injunction or filing such infringement action after consulting with Merck. Except as otherwise provided in this Section 7.4.5, any such action shall be subject to the terms and conditions of Section 7.4.1 through 7.4.4 in relation to actions for infringement brought by Merck.

(vi) The Parties recognize that procedures other than those set forth above in Section 7.4.5 may apply with respect to Biosimilar Applications. In the event that the Parties determine that certain provisions of Applicable Laws in the United States or in any other country in the Territory apply to actions taken by the Parties with respect to Biosimilar Applications under Section 7.4.5 in such country, the Parties shall comply with any such Applicable Laws in such country (and any relevant and reasonable procedures established by Parties) in exercising their rights and obligations with respect to Biosimilar Applications under this Section 7.4.5

(b) As used herein, the term "**Biosimilar Application**" means an application or submission filed with a Regulatory Authority for Marketing Authorization of a pharmaceutical or biological product claimed to be biosimilar or interchangeable to any Product or otherwise

relying on the approval of such Product, including, for example, an application filed under 42 U.S.C. §262(k).

7.4.6 **Merck Patent Rights and Merck Know-How**. Notwithstanding the foregoing provisions of this Section 7.4, Merck shall have the sole right, in its discretion, to handle any action with respect to any infringement of Merck Patent Rights, or misappropriation of Merck Know-How, including that Merck shall have the sole right, in its discretion, to handle any certification matter regarding any Merck Patent Rights with respect to any Biosimilar Application as set forth in Section 7.4.5, and NewLink shall have no rights in connection with any of the foregoing. For any action with respect to any infringement of Merck Patent Rights or misappropriation of Merck Know-How (including in connection with any Biosimilar Application), in the event that Merck is unable to initiate or prosecute such action solely in its own name, NewLink shall, at Merck's request and expense, join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to initiate litigation to prosecute and maintain such action. In connection with any action, at the request of Merck, NewLink shall, at Merck's expense, provide Merck with reasonable assistance that Merck may reasonably request. As between the Parties, any recovery obtained by Merck in connection with or as a result of any action contemplated by the provisions of this Section 7.4.6, whether by settlement or otherwise, shall be retained solely by Merck. In all cases, NewLink shall give Merck prompt written notice of any infringement of any Merck Patent Rights that may come to its attention and/or any certification regarding any Merck Patent Rights it has received or otherwise becomes aware in connection with any Biosimilar Application (and NewLink shall provide Merck with a copy of such certification within [*] of receipt).

7.5 **Patent Term Extension**. NewLink shall reasonably cooperate with Merck, including providing reasonable assistance to Merck (including executing any documents as may reasonably be required), in efforts to seek and obtain patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Joint Program Patent Rights, NewLink Patent Rights or Merck Patent Rights, including as may be available to the Parties under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States of America, in each case, in connection with the Products. In the event that elections with respect to obtaining such patent term restoration or supplemental protection certificates or their equivalents are to be made in relation to Joint Program Patent Rights or NewLink Patent Rights or Merck Patent Rights, Merck shall have the right to make the election and NewLink agrees to abide by such election.

7.6 **Other Patent Cooperation**. At the request of [*] shall reasonably cooperate with [*] with respect to patent protection with respect to the Program Know-How, including to take reasonable actions [*] for United States patents and patent applications, in each case, as determined by [*].

7.7 **Infringement or Misappropriation Claims with Respect to Compound or Product**. NewLink shall give Merck prompt written notice if any Third Party asserts, or if NewLink otherwise becomes aware, that a Third Party's Patent Rights or Know-How may be infringed or misappropriated by the research, development, making, using, selling, offering for sale, importing, exporting or otherwise exploiting any Compounds or Products. Subject to the provisions of Section 9.1.1 (Indemnity-Merck) and 9.1.2 (Indemnity-NewLink), Merck shall have the sole right (regardless of whether notified by NewLink pursuant to the foregoing provisions of this Section 7.7), but not the obligation, using counsel of its choice, to control the defense of any infringement or misappropriation action (including any declaratory judgment action) brought by a Third Party relating to the infringement or misappropriation of a Third Party's Patent Rights or Know-How or other intellectual property by the research, development, making, using, selling, offering for sale, importing, exporting or otherwise exploiting any Compounds or Products, and NewLink shall have no rights, and shall not take any actions, in connection therewith. In connection with any such action, NewLink shall cooperate fully with Merck and NewLink will provide Merck with any information or assistance that Merck may request, and in the event that Merck is unable to bring such action solely in its own name, NewLink shall join such action voluntarily and execute and cause its Affiliates to execute all documents necessary for Merck to bring such action.

ARTICLE 8TERM AND TERMINATION

8.1 **Term and Expiration**. This Agreement shall become effective upon the Effective Date and, if not otherwise terminated earlier pursuant to this Article 8, shall expire on a Product-by-Product basis upon the expiration of the royalty payment obligations hereunder with respect to the applicable Product (the "**Term**"). This Agreement shall expire in its entirety (if not otherwise terminated earlier pursuant to this Article 8) on the date that this Agreement has expired with respect to all Products. Upon expiration of this Agreement with respect to a given Product under this Section 8.1, [*], and, upon expiration of this Agreement in its entirety under this Section 8.1, [*].

8.2 **Other Termination**.

8.2.1Merck shall have the right to terminate this Agreement at any time in its sole discretion by giving [*] advance written notice to NewLink; provided, however, that such termination shall be effective immediately if Merck elects to terminate this

Agreement for [*] (a "**Safety Termination**"). The Parties hereby acknowledge and agree that in the event that Merck delivers notice of termination to NewLink pursuant to this Section 8.2.1, but prior to such termination becoming effective, [*], then, notwithstanding [*] or anything to the contrary contained herein, [*].

8.2.2 If, at any time during the Term, a BLA has not been submitted for at least one (1) Product and Merck [*] for an Alternative Product, NewLink shall have the right to terminate this Agreement on [*] advance written notice to Merck with respect to all Products other than [*]; provided that such notification of NewLink's exercise of its termination right under this Section 8.2.2 shall be provided within [*] for [*] Alternative Product. As used herein, "**Alternate Product**" shall mean [*].

8.3 **Termination for Cause**.

8.3.1 **Cause for Termination**. This Agreement may be terminated at any time during the Term:

(a) upon written notice by NewLink if Merck is in material breach of (i) its Product Diligence Obligations pursuant to Section 3.5.1 by causes and reasons within its control or (ii) any obligation to make payments to NewLink hereunder, and has not cured such breach within [*] after written notice requesting cure of the breach (provided, however that such initial [*] cure period shall be extended for an additional [*] for so long as [*]; provided, however, in the event of a good faith dispute with respect to the existence of a material breach, the [*] cure period shall be tolled until such time as the dispute is resolved pursuant to Section 10.6; provided further, however, that it is agreed that termination pursuant to this Section 8.3.1(a) shall be on a Product-by-Product basis to which the breach relates and that NewLink cannot terminate this Agreement under this Section 8.3.1(a) with respect to the non-affected Products (and the effects of termination in Section 8.3.2 shall only apply with respect to such terminated Product); or

(b) by a Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors, by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [*] after the filing thereof (an "**Insolvency Event**").

8.3.2 **Effect of Termination**. Upon termination (but not expiration) of this Agreement for any reason (other than termination by Merck pursuant to Section 8.3.1(b)), all licenses and other rights granted hereunder shall terminate (except those that

expressly survive as set forth in Section 8.4). In addition in such case, [*] the following consequences shall apply; provided that if this Agreement is terminated only with respect to a particular Product or Product(s) the following shall apply solely with respect to such Product or Product(s):

(a) **Terminated Products**. Following termination NewLink may elect to receive (which election shall be made in writing to Merck within [*] following termination), and Merck hereby grants to NewLink, effective upon such election, [*]) to research, develop, import, use, make, have made, offer for sale and sell the Current Product (if this Agreement is terminated with respect to the Current Product) and any other Product [*], but excluding [*] (such Products, [*] "**Terminated Products**"), in each case, in the Field in the Territory. In consideration for such license, the Parties shall agree to, [*] shall be [*]. If the Parties are unable to agree [*], either Party [*] and all of [*]. Each Party shall [*], and the [*]. The Parties shall [*] and the [*]. Notwithstanding the provisions of this Section 8.3.2(a), the licenses in this Section 8.3.2(a) shall not be effective until such time as the Parties agree [*].

(b) **Regulatory Documentation.** Promptly following the effective date of such termination, Merck shall transfer and assign to NewLink all of its (and its Affiliates) material Regulatory Documentation and data relating solely and exclusively to any Terminated Products (provided, however, that if there is additional Regulatory Documentation or data in Merck's (or its Affiliates) Control related to the Terminated Products that is necessary for NewLink to continue to Develop and Commercialize such Terminated Product, then at the written request of NewLink (which request shall be made within [*] following the effective date of termination), Merck shall use Commercially Reasonable Efforts to provide NewLink with access to such Regulatory Documentation and data (provided that Merck may redact any and all portions thereof not related to the Terminated Product)), in each case, to the extent [*].

(c) **Transition Assistance.** Merck shall, [*], provide the following transitional assistance upon request by NewLink:

(i) Merck shall promptly destroy or return to NewLink all Know-How, data, materials and other Confidential Information made available to Merck by NewLink under this Agreement.

(ii) Merck shall, at NewLink's request, provide to NewLink (including when available, in electronic format) a copy of the physical embodiment of all Merck Know-How that is directly related to any Terminated Product and licensed to NewLink pursuant to Section 8.3.2(a); provided that NewLink shall comply with the confidentiality and non-use provisions set

forth in Article 4 with respect to such Merck Know-How, and NewLink shall only use such Merck Know-How in accordance with the licenses pursuant to Section 8.3.2(a).

(iii) Merck shall [*] all inventory of Terminated Product in Merck's (or its Affiliate's) possession, and in connection therewith, [*].

(iv) Merck shall assign back to NewLink any [*] that relate solely and exclusively to the Terminated Product.

(v) Merck shall assign or transfer to NewLink any manufacturing agreement between Merck and a Third Party contract manufacturer with respect to such Terminated Product, to the extent assignable (and solely to the extent that such manufacturing agreement does not relate to any other products).

(d) **[*]; Other Provisions**. Notwithstanding the foregoing provisions of this Section 8.3.2, any [*] to provide [*] shall not [*]. All Regulatory Documentation, Know-How, data, information, correspondence and other items provided to NewLink pursuant to this Section 8.3.2 shall be provided [*], and shall [*]. NewLink shall provide reasonable assistance to Merck in connection with the transfer and delivery of the foregoing items.

(e) **Wind-Down**. Notwithstanding the foregoing provisions of this Section 8.3.2, the licenses granted to Merck pursuant to Section 3.1 and Section 3.2 shall survive for [*] following the effective date of termination in order for Merck (and its Affiliates, sublicensees and distributors), [*], during the [*] period immediately following the effective date of termination, to (i) finish or otherwise wind-down any ongoing Clinical Trials with respect to any Compounds or Products hereunder or transfer such Clinical Trials (where Merck is permitted to do so under Applicable Laws) to NewLink and (ii) finish any work-in-progress and sell any Products or Compounds remaining in inventory, in accordance with the terms of this Agreement; provided that, for clarity, [*] and; provided further, that such licenses shall be non-exclusive.

8.3.3 **Effect of Termination by Merck for Insolvency Event**. In the event that this Agreement is terminated by Merck under Section 8.3.1(b) then the provisions of this Section 8.3.3 shall apply (and the provisions of Section 8.3.2 shall not apply). In the event that this Agreement is terminated due to the rejection of this Agreement by or on behalf of NewLink due to an Insolvency Event (including under Section 365 of the United States Bankruptcy Code (the "**Code**"), as applicable), all licenses and rights to licenses granted under or pursuant to this Agreement by NewLink to Merck are and shall otherwise be deemed to be (including for purposes of Section 365(n) of the Code, as applicable) licenses of rights to "intellectual

property" (including as defined under Section 101(35A) of the Code, as applicable). The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under any applicable insolvency statute (including the Code), and that upon commencement of an Insolvency Event by or against NewLink, Merck shall be entitled to a complete duplicate of or complete access to (as Merck deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Merck (i) upon any such commencement of a bankruptcy proceeding upon written request therefore by Merck, unless NewLink elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of NewLink, then upon written request therefore. The provisions of this Section 8.3.3 shall be (1) without prejudice to any rights Merck may have arising under any applicable insolvency statute or other Applicable Law (including the Code, as applicable) and (2) effective only to the extent permitted by Applicable Law (including the Code, as applicable).

8.4 **Effect of Expiration or Termination; Survival**. Subject to a Party's continuing right to use and disclose Confidential Information of the other Party under the surviving license pursuant to this Article 8, if any, following expiration or any early termination of this Agreement, each Party shall destroy, and confirm in writing that is has destroyed, all Confidential Information in tangible form and substances or compositions delivered or provided by the other Party, as well as any other material provided by the other Party in any medium (provided, however, that the receiving Party may keep one copy of Confidential Information received from the other Party in its confidential legal archives to confirm compliance with the non-use and non-disclosure provisions of this Agreement). Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Each Party shall pay all amounts then due and owing as of the expiration or termination date. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination. The provisions of Sections 4.1, 4.2, 4.4, 4.5, 4.6.1, 4.9 and 4.10 shall survive the expiration or termination of this Agreement and shall continue in effect for [*]. In addition, the provisions of Articles 1 (as necessary for the interpretation of the other surviving provisions), 9 and 10, and Sections 2.9.4 (but solely with respect to the penultimate sentence thereof), 2.10.1, 2.10.2, 5.3 (but solely with respect to any [*] or [*], as applicable, received during the Term, and excluding Section 5.3.3), 5.4 (solely with respect to Product Net Sales hereunder prior to the effective date of termination or Product Net Sales by Merck under Section 8.3.2(e), but in each case, solely

to the extent royalties would otherwise be payable on such Product Net Sales in accordance with Section 5.4), 5.5, 5.6, 5.7, 6.4, 7.1, 7.2, 8.1, 8.3.2, 8.3.3 and this Section 8.4 shall survive any expiration or termination of this Agreement.

ARTICLE 9 INDEMNITY; LIMITATIONS ON LIABILITY

9.1 **Indemnity; Insurance**.

9.1.1 **Merck**. Merck shall indemnify, defend and hold NewLink and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "**NewLink Indemnitees**") harmless from and against any losses, costs, claims, damages, liabilities or expense (including reasonable attorneys' and professional fees and other expenses of litigation) (collectively, "**Liabilities**") arising, directly or indirectly out of or in connection with Third Party claims, suits, actions, demands or judgments (a "**Third Party Claim**") relating to (a) any breach by Merck of its representations, warranties or covenants made in this Agreement, (b) the gross negligence or willful misconduct of Merck, its Affiliates or their respective officers, directors, agents or employees, in performing any obligations under this Agreement or (c) the Development, Manufacture or Commercialization of any Compound or Product by or on behalf of Merck or Related Parties; except, in each case, to the extent such Liabilities result from a breach of this Agreement by NewLink or the negligence or willful misconduct of NewLink or other NewLink Indemnitees, or to the extent NewLink has an obligation to indemnify Merck Indemnitees under Section 9.1.2(a), (b), (c), (d) or (e).

9.1.2 **NewLink**. NewLink shall indemnify, defend and hold Merck and its Affiliates and their respective directors, officers, employees, agents and their respective successors, heirs and assigns (the "**Merck Indemnitees**") harmless from and against any Liabilities arising, directly or indirectly out of or in connection with Third Party Claims relating to (a) any breach by NewLink of its representations, warranties or covenants made in this Agreement, (b) the gross negligence or willful misconduct of NewLink, its Affiliates or their respective officers, directors, agents or employees, in performing any obligations under this Agreement, (c) the Development or Manufacture of any Compound or Product prior to the Effective Date, (d) any breach by NewLink of the NewLink Third Party Agreements; or (e) the Development, Manufacture or Commercialization of any Terminated Product; except, in each case, to the extent such Liabilities result from a breach of this Agreement by Merck, or the negligence or willful misconduct of Merck or other Merck Indemnitees, or to

the extent Merck has an obligation to indemnify NewLink Indemnitees under Section 9.1.1(a) or (b).

9.1.3**Procedure**. If a Party is seeking indemnification under this Article 9 (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to this Article 9 as soon as reasonably practicable after receiving notice of the claim (provided, however, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party's rights to indemnification under this Article 9, except to the extent that such delay or failure materially prejudices the Indemnifying Party's ability to defend against the relevant claims). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. The Indemnifying Party shall not settle any claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld. The Indemnified Party shall not settle or compromise any such claim without the prior written consent of the Indemnifying Party, which it may provide in its sole discretion. If the Parties cannot agree as to the application of Section 9.1.1 or 9.1.2 to any claim, pending resolution of the dispute pursuant to Section 10.6, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 9.1.1 or 9.1.2 upon resolution of the underlying claim.

9.1.4**Insurance**. Each Party shall procure and maintain insurance, including product liability insurance (or self-insure), adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Section 9.1 or otherwise. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [*] prior to the cancellation, non renewal or material change in such insurance or self insurance which materially adversely affects the rights of the other Party hereunder. Notwithstanding the foregoing, the foregoing provisions shall not apply to Merck if Merck self-insures.

9.2 **Limitation of Liability**. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES (INCLUDING LOST PROFITS OR LOST REVENUES) ARISING FROM OR RELATING TO THIS AGREEMENT (INCLUDING BREACH OF THIS AGREEMENT) OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 9.2 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (1) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 9.1.1, 9.1.2 OR 2.9.4 IN CONNECTION WITH ANY THIRD PARTY CLAIMS, OR (2) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 4.

ARTICLE 10 MISCELLANEOUS

10.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

10.2 **Assignment; Change of Control**.

10.2.1 **Assignment**. Except as provided in this Section 10.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; provided, that a Party may, without such consent, assign this Agreement and its rights and obligations hereunder (i) to an Affiliate (provided, however, that a Party assigning to an Affiliate shall remain fully and unconditionally liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate), and the assigning Party shall promptly notify the other Party in writing of any such assignment, or (ii) subject to Section 10.2.3, in connection with the transfer or sale of all or substantially all of its assets to which this Agreement relates, or (iii) subject to Section 10.2.3, in connection with

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

a Party's Change of Control (including, with respect to NewLink, any Change of Control of NL); provided that, in connection with any such assignment by NewLink to a Third Party pursuant to the foregoing clauses (ii) or (iii), as applicable, [*]. Any attempted assignment not in accordance with this Section 10.2 shall be void. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.

10.2.2 **Exceptions to Assignment by NewLink [*]**. Notwithstanding the provisions of Section 10.2.1, neither NewLink nor its Affiliate shall be permitted to assign this Agreement (or its rights and obligations hereunder) [*]. However, [*] pursuant to [*] provided that [*] (a "[*****]"). For clarity, such [*] shall thereafter also be [*].

10.2.3 **Change of Control of NewLink**. In the event of a Change of Control of NL or NewLink (or in the event of any assignment of this Agreement by NewLink pursuant to clause (ii) of Section 10.2.1), NewLink must notify Merck in writing at least [*] prior to completion of any such Change of Control (to the extent such notification is legally permissible prior to completion of such Change of Control, and if such notification is not legally permissible prior to such Change of Control, then such notification shall be provided to Merck in writing [*] with respect to such Change of Control) or assignment, as applicable, and, where the Third Party counterparty to such Change of Control (or assignment, as applicable) is [*] (a "**Competitor**"), Merck shall have the right, at any time within [*] of receipt of such notice, to elect [*] upon written notice to NewLink: (i) [*]; provided that (a) [*] effective upon such termination and (b) to the extent [*] as part of the [*]; (ii) require NewLink, including its acquiring party, to adopt reasonable procedures to be agreed upon in writing with Merck, such agreement not to be unreasonably withheld, to prevent the disclosure of all Confidential Information of Merck and its Affiliates and other information with respect to the Development, Manufacturing and Commercialization of Compounds or Products (the "**Sensitive Information**") beyond [*] or, where [*] in order for [*] hereunder and that [*], and to control the dissemination of Sensitive Information disclosed after the NewLink Change of Control, which procedures shall include reasonable restrictions on the scope of any Sensitive Information to be provided by Merck; (iii) [*]; (iv) [*] hereunder to [*] as is necessary for NewLink to [*]; and/or (v) request NewLink (or its Affiliate, as applicable) to [*], and in such case, [*], to the extent legally permitted, [*]. No Patent Rights, Know-How or other intellectual property rights owned or otherwise controlled by the Third Party acquiror (or any Affiliates of such Third Party prior to such Change of Control, but excluding, for clarity, NewLink and Affiliates of NewLink prior to such Change of Control) acquiring NewLink or NL pursuant to a Change of Control shall be included in the

rights licensed hereunder or otherwise subject to this Agreement; provided that, for clarity, all Patent Rights, Know-How and other intellectual property licensed to Merck hereunder prior to such Change of Control (or otherwise coming under the Control of NewLink (or any of its Affiliates that were Affiliates prior to such Change of Control) following such Change of Control) shall, in all cases, continue to be licensed to Merck hereunder.

10.3 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

10.4 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to NewLink, to:	BioProtection Systems Corporation C/O NewLink Genetics Corporation 2503 South Loop Drive Suite 5100 Ames, IA 50010 Attention: Chief Financial Officer Facsimile No. [*]
and	NewLink Genetics Corporation 2503 South Loop Drive Suite 5100 Ames, IA 50010 Attn: Chief Financial Officer Facsimile No. [*]
with a copy to:	Cooley LLP One Freedom Square Reston Town Center 11951 Freedom Drive Reston, VA 20190-5656 Attn: Kenneth J. Krisko Fax: [*]
if to Merck, to:	Merck Sharp & Dohme Corp. One Merck Drive P.O. Box 100, WS3A-65 Whitehouse Station, NJ 08889-0100 Attention: Office of Secretary Facsimile No.: [*]
and	Merck Sharp & Dohme Corp. One Merck Drive P.O. Box 100 Whitehouse Station, NJ 08889-0100 Attention: Vice-President, Business Development and Licensing, Merck Research Laboratories Facsimile No.: [*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given (a) when delivered if personally delivered or sent by facsimile on a business

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

day (or if delivered or sent on a non-business day, then on the next business day), (b) on the business day after dispatch if sent by nationally-recognized overnight courier, or (c) on the [*] day following the date of mailing, if sent by mail. To the extent practicable, the Party delivering a notice shall also send a copy of such notice to the Project Leader of other the Party.

10.5 **Applicable Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws or renvoi.

10.6 **Dispute Resolution**.

10.6.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an "**Excluded Claim**" shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association ("**AAA**"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

10.6.2 The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: within [*] after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within [*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York. All proceedings and communications shall be in English.

10.6.3 Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

10.6.4 Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York law statute of limitations.

10.6.5 The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

10.6.6 As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright, or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

10.7 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

10.8 **Independent Contractors**. It is expressly agreed that NewLink and Merck shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither NewLink nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

10.9 **Waiver**. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

10.10 **Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

10.11 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the

rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

10.12 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Attachment or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Attachment or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", "hereunder" and derivative or similar words refer to this Agreement, including the Attachments, as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation", (e) the word "or" shall not be construed as exclusive, (f) the word "law" or "laws" means any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body) and (g) references to any Articles or Sections include Sections and subsections that are part of the reference Article or section (e.g., a section numbered "Section 2.2.1" would be part of "Section 2.2.", and references to "Article 2" or "Section 2.2." would refer to material contained in the subsection described as "Section 2.2.2"). In addition, any payment which is deemed to be non-creditable or non-refundable shall not in any way limit Merck's right to indemnification under this Agreement or to otherwise recover damages for breach of this Agreement.

10.13 **Counterparts**. 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. In addition, this Agreement may be executed by facsimile or "PDF" and such facsimile or "PDF" signature shall be deemed to be an original.

10.14 **Entire Agreement; Amendments. This Agreement, together with the Schedules and** other attachments hereto, contains the entire understanding of the Parties with respect to the Transition Program and the licenses and rights granted hereunder. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter of this Agreement, including the Transition Program and the licenses and rights granted hereunder, are superseded by the terms of this Agreement. The Schedules and other attachments to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended,

or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto.

10.15 **Further Actions**. Each Party will execute, acknowledge and deliver such further instruments, and to do all such other ministerial, administrative or similar acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

10.16 **No Third Party Rights**. The provisions of this Agreement are for the exclusive benefit of the Parties, and no other person or entity shall have any right or claim against any Party by reason of these provisions or be entitled to enforce any of these provisions against any Party.

10.17 **Expenses**. Except as otherwise specifically provided in this Agreement, each Party (and its Affiliates) shall bear its own costs and expenses in connection with entering into this Agreement and the consummation of the transactions and performance of its obligations contemplated hereby.

10.18 **Extension to Affiliates**. Merck shall have the right to extend the rights, licenses, immunities and obligations granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to Merck. Merck shall remain fully liable for any acts or omissions of such Affiliates.

10.19 **Parent Guarantee.** This Agreement provides for the performance by NewLink, an Affiliate of NL. NL hereby unconditionally and irrevocably guarantees, and shall be fully liable for, the prompt and complete performance (including any amounts payable hereunder) of this Agreement, as may be amended from time to time, by NewLink. The performance guaranty described in this Section 10.19 shall be effective [*] as to which [*]. NL's obligations are [*] of any [*] and it shall not be necessary for [*] as a condition to the [*]. NL, hereby [*] to [*] that any other [*] and expressly [*] that it may have [*].

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERCK SHARP & DOHME CORP.

By: /s/ Rita A. Karachun

Name: Rita A. Karachun

Title: President

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link Jr., MD

Name: Charles J. Link Jr., MD

Title: CEO

BIOPROTECTION SYSTEMS CORPORATION

By: /s/ Charles J. Link Jr., MD

Name: Charles J. Link Jr., MD

Title:

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.26

Current Compound

The Current Compound means the following [*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.72

NewLink Existing Funding Agreements

[*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.73

NewLink Existing Manufacturing Agreements

ATTACHMENT 1 [*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.79

NewLink Patent Rights

[*]

[*]

[*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.122

Transition Plan Outline

(See Attached)

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 1.122 – Transition Plan Outline

[*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 3.1.3

Certain Terms of NewLink Canada License Amendment

[*]

ATTACHMENT 2

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 3.10

NewLink Future Funding Agreements

- [*]
- [*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 4.6

Form of Press Release

(See Attached)

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

News Release

FOR IMMEDIATE RELEASE

Merck Media Contacts: **Investor Contacts:**

Pam Eisele (267) 305-3558
NewLink Genetics: Jack Henneman (515) 598-2561

Imraan Munshi (215) 652-0059
Merck: Justin Holko (908) 423-5088

Merck and NewLink Genetics Enter into Licensing and Collaboration Agreement for Investigational Ebola Vaccine

Clinical Development, Manufacturing Expertise, and Scale Critical to Success

WHITEHOUSE STATION, N.J. and AMES, I.A., Nov. XX, 2014 – Merck (NYSE:MRK), known as MSD outside the United States and Canada, and NewLink Genetics Corporation (NASDAQ: NLNK), announced today that they have entered into an exclusive worldwide license agreement to research, develop, manufacture, and distribute NewLink's investigational rVSV-EBOV (Ebola) vaccine candidate.

The vaccine candidate, originally developed by the Public Health Agency of Canada (PHAC), is currently being evaluated in Phase I clinical trials. Pending the results of ongoing Phase I trials in the U.S. National Insitutes of Health (NIH) has announced plans ot initiate, in early 2015, a large randomized, controlled Phase III study to evaluate the safety and efficacy of the rVSV-EBOV vaccine and another investigational Ebola vaccine co-developed by the National Institute of Allergy and Infectious Diseases (NIAID) and GlaxoSmithKline.

"Effective Ebola vaccines will be a critical component of comprehensive prevention and control measures for people at risk of Ebola virus infection and to stem future outbreaks globally," said Dr. Julie Gerberding, president of Merck Vaccines. "Merck is committed to applying our vaccine expertise to address important global health needs and, through our

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

collaboration with NewLink, we hope to advance the public health response to this urgent international health priority."

According to Dr. Charles Link, chairman and chief executive officer of NewLink Genetics, "Merck's vaccine development expertise, commercial leadership and history of successful strategic alliances make it an ideal partner to expedite the development of rVSV-ZEBOV and, if demonstrated to be efficacious and well-tolerated, to make it available to individuals and communities at risk of Ebola virus infection around the world."

Under the terms of the agreement, Merck will be granted the exclusive rights to the rVSV-EBOV vaccine candidate as well as any follow-on products. The vaccine candidate is under an exclusive licensing arrangement with a wholly-owned subsidiary of NewLink Genetics. Under these license arrangements, the PHAC retains non-commercial rights pertaining to the vaccine candidate.

Phase I clinical trials of the rVSV-EBOV vaccine are now underway at the Walter Reed Army Institute of Research and the NIAID at the NIH. Additional Phase I studies are underway or planned to begin in the near future at clinical research centers in Switzerland, Germany, Kenya and Gabon in a World Health Organization-coordinated effort, and in Canada by the Canadian Immunization Research Network.

"This vaccine is the result of years of hard work and innovation by Canadian scientists. We are pleased that this new alliance coupled with the clinical trials currently underway will further strengthen the possibility that the vaccine will make a difference in global response to the Ebola outbreak," said Canada's Minister of Health, Rona Ambrose.

About rVSV Vaccine Platform

This vaccine platform is based on an attenuated strain of vesicular stomatitis virus that has been modified to express an Ebola virus protein that plays an essential role in establishing virus infection. The rVSV-EBOV vaccine was created by scientists at the Public Health Agency of Canada's National Microbiology Laboratory. A significant portion of the funding for the further development of the vaccine came from the CBRN Research and Technology Initiative, a federal program led by Defence Research and Development Canada. In 2010, PHAC signed a licensing arrangement with BioProtection Systems (BPS), a wholly-owned subsidiary of NewLink Genetics, as the sole licensee for these vaccines and the underlying technology. BPS has worked with the PHAC to produce clinical trial materials and to move this vaccine candidate into Phase I studies.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

About NewLink Genetics Corporation

NewLink is a biopharmaceutical company focused on discovering, developing and commercializing novel immuno-oncology products to improve treatment options for patients with cancer. NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. BioProtection Systems, a wholly-owned subsidiary of NewLink Genetics Corporation, is focused on the research, development and commercialization of vaccines. BPS is focused on control of emerging infectious diseases, including improvement of existing vaccines and providing rapid-response prohylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics of acts of bioterrorism. For more information please visit http://www.linkp.com.

Merck Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2013 Annual Report on Form 10-K and the company's other filings with the SEC available at the SEC's Internet site (www.sec.gov).

NewLink Genetics Corporation Forward-Looking Statement

This press release contains forward-looking statements of NewLink that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek," 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. These forward-looking statements include, among others, statements regarding plans to develop and commercialize our product candidates and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink's Annual Report on Form 10-K for the period ended December 31, 2013, and subsequent filings with the Securities and Exchange Commission. The forward-looking statements in this press release represent NewLink's views as of the date of this press release. NewLink anticipates that subsequent events and developments will cause its views to change.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink's views as of any date subsequent to the date of this press release.

# # #

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 5.4.9

NewLink Wire Instructions

[*]

Account Name: [*]
Account Number: [*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 6.2.12

Third Party Clinical Studies

[*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 6.2.21

Product Materials

[*]

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Schedule 6.2.26

NewLink Affiliates

NewLink International

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Exhibit 10.106

Iowa State University Research Park Corporation
2711 South Loop Drive, Suite 4050
Ames, Iowa 50010-8648

Memorandum of Agreement

DATE: October 25, 2014

TO: Carl Langren
BioProtection Systems Corporation
2503 S. Loop Drive, Suite 5100
Ames, IA 50010

FROM: Steven T. Carter, President

RE: ADDENDUM TO THE LEASE BETWEEN ISU RESEARCH PARK CORPORATION AND BIOPROTECTION SYSTEMS CORPORATION DATED AUGUST 22, 2005.

The following information constitutes additions to the Lease Agreement between ISU Research Park Corporation (Landlord) and BioProtection Systems Corporation (Tenant). Upon signatures of appropriate representatives of Landlord and Tenant affixed to this Memorandum, this Memorandum becomes a part of that Lease Agreement dated August 22, 2005.

Tenant has requested and Landlord agrees to extend the lease for Suite 3900 (±3,147 rsf) in the following manner:

Term	Sq. Ft. Base Rents	Sq. Ft. Operating Rents	Monthly Base Rents	Monthly Operating Rents	Annual Base Rents	Annual Operating Rents
11/1/2014-10/31/2015	$12.75	Actual	$3,343.69	Actual	$40,124.28	Actual

Tenant leases the space as is. Any modifications will be at the Tenant's sole expense. Landlord agrees to release Tenant from this lease obligation upon Tenant's move into another facility at the ISU Research Park. Gas & water usage, as well as utility costs for the HVAC system, will be prorated & invoiced monthly. Electricity is metered separately & is invoiced directly from the provider. Subject to the terms of this Memorandum, Tenant agrees that all terms and conditions of the August 22, 2005 Lease and those described in this Memorandum shall remain in force.

Please sign and return both originals to my office by October 10, 2014 if you concur with the above terms. We will then send a fully executed copy for your records.

AGREED

FOR	FOR
BioProtection Systems Corp.	ISU Research Park Corporation
/s/ Carl Langren	/s/ Steven Carter
Senior VP of Finance	Director
Title	Title
10/25/2014	10/27/2014
Date	Date

Exhibit 10.107

Iowa State University Research Park Corporation
2711 South Loop Drive, Suite 4050
Ames, Iowa 50010-8648

Memorandum of Agreement

DATE: December 29, 2014

TO: Carl Langren, CFO
NewLink Genetics Corporation
2503 S. Loop Drive, Suite 5100
Ames, IA 50010

FROM: Steven T. Carter, President

RE: ADDENDUM TO THE LEASE BETWEEN ISU RESEARCH PARK CORPORATION AND NEWLINK GENETICS CORPORATION DATED MARCH 1, 2010.

The following information constitutes changes to the Lease Agreement between ISU Research Park Corporation (Landlord) and NewLink Genetics Corporation (Tenant). Upon signatures of appropriate representatives of Landlord and Tenant affixed to this Memorandum, this Memorandum becomes a part of that Lease Agreement dated March 1, 2010.

Tenant has requested and Landlord agrees to lease Suite 2140 (±6,770 rentable square feet), Building #2 at 2625 North Loop Drive, in the following manner:

Term	Sq. Ft. Base Rents	Sq. Ft. Operating Rents	Monthly Base Rents	Monthly Operating Rents	Annual Base Rents	Annual Operating Rents
2/1/2015-1/31/2018	$10.50	Actual	$5,923.75	Actual	$71,085.00	Actual

Tenant leases the space as is. Any modifications will be at the Tenant's sole expense. Tenant is responsible for all utility costs and operations. Subject to the terms of this Memorandum, Tenant agrees that all terms and conditions of the March 1, 2010 Lease and those described in this Memorandum shall remain in force.

Please sign and return both originals to my office by December 19, 2014 if you concur with the above terms. We will then send a fully executed copy for your records.

AGREED

FOR	FOR
NewLink Genetics Corporation	ISU Research Park Corporation
/s/ Carl Langren	/s/ Steven Carter
VP Finance	Director
Title	Title
12/29/2014	12/29/2014
Date	Date

Exhibit 10.108

Iowa State University Research Park Corporation
2711 South Loop Drive, Suite 4050
Ames, Iowa 50010-8648

Memorandum of Agreement

DATE: February 12, 2015

TO: Carl Langren, CFO
NewLink Genetics Corporation
2503 S. Loop Drive, Suite 5100
Ames, IA 50010

FROM: Steven T. Carter, President

RE: ADDENDUM TO THE LEASE BETWEEN ISU RESEARCH PARK CORPORATION AND NEWLINK GENETICS CORPORATION DATED MARCH 1, 2010.

The following information constitutes changes to the Lease Agreement between ISU Research Park Corporation (Landlord) and NewLink Genetics Corporation (Tenant). Upon signatures of appropriate representatives of Landlord and Tenant affixed to this Memorandum, this Memorandum becomes a part of that Lease Agreement dated March 1, 2010.

Tenant has requested and Landlord agrees to extend the Lease Agreement for Suites 5100- 5400 (±23,544 rentable square feet), Building #5 at 2503 South Loop Drive, in the following manner:

Term	Sq. Ft. Base Rents	Sq. Ft. Operating Rents	Monthly Base Rents	Monthly Operating Rents	Annual Base Rents	Annual Operating Rents
2/1/2015-1/31/2020	$11.50	Actual	$22,563.00	Actual	$270,756.00	Actual

Tenant leases the space as is. Any modifications will be at the Tenant's sole expense. Tenant will continue to be responsible for all utility costs and operations. Subject to the terms of this Memorandum, Tenant agrees that all terms and conditions of the March 1, 2010 Lease and those described in this Memorandum shall remain in force.

Please sign and return both originals to my office if you concur with the above terms. We will then send a fully executed copy for your records.

AGREED

FOR	FOR
NewLink Genetics Corporation	ISU Research Park Corporation
/s/Carl Langren	/s/Steven Carter
VP Finance	Director
Title	Title
2/12/2015	2/12/2015
Date	Date

Exhibit 21.1

SUBSIDIARIES OF NEWLINK GENETICS CORPORATION

Subsidiary	Jurisdiction of Incorporation
BioProtection Systems Corporation	Delaware
NewLink International	Cayman Islands

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
NewLink Genetics Corporation:

We consent to the incorporation by reference in the registration statements (No. 333-178032, No. 333-184880, No. 333-185721, and No. 333-186020) on Form S-8 and Form S-3 of NewLink Genetics Corporation of our report dated March 16, 2015, with respect to the consolidated balance sheets of NewLink Genetics Corporation and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations, equity, and cash flows for each of the years in the three-year period ended December 31, 2014, and the effectiveness of internal control over financial reporting as of December 31, 2014, which report appears in the December 31, 2014, annual report on Form 10-K of NewLink Genetics Corporation.

/s/ KPMG LLP

Des Moines, Iowa
March 16, 2015

EXHIBIT 31.1

CERTIFICATION

I, Charles J. Link, Jr., certify that:

1. I have reviewed this annual report on Form 10-K of NewLink Genetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2015

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, John B. Henneman III certify that:

1. I have reviewed this annual report on Form 10-K of NewLink Genetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2015

By: /s/ John B. Henneman III

John B. Henneman III

Chief Financial Officer

(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Charles J. Link, Jr., Chief Executive Officer of NewLink Genetics Corporation (the "Company"), and John B. Henneman, III, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2014, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 16, 2015

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)

By: /s/ John B. Henneman III
John B. Henneman III
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its Staff upon request. This certification "accompanies" the
Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.