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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-Q**

**Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

For the quarterly period ended June 30, 2015.

**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**

(State or other jurisdiction of incorporation or organization)

**42-1491350**

(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)

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

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

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

(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  No

As of July 29, 2015, there were 28,718,371 shares of the registrant's Common Stock, par value \$0.01 per share, outstanding.



**NewLink Genetics Corporation**

**FORM 10-Q**

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## PART I

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

	<b>June 30, 2015</b>	<b>December 31, 2014</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 203,377	\$ 190,404
Certificates of deposit	4,202	12,393
Prepaid expenses	11,344	8,333
Income tax receivable	2,519	15,604
State research and development credit receivable	440	13
Other receivables	12,570	3,716
Total current assets	<u>234,452</u>	<u>230,463</u>
<b>Leasehold improvements and equipment:</b>		
Leasehold improvements	6,139	6,022
Computer equipment	2,220	1,399
Lab equipment	4,954	4,110
Contract manufacturing organization equipment	1,067	1,023
Total leasehold improvements and equipment	<u>14,380</u>	<u>12,554</u>
Less accumulated depreciation and amortization	<u>(5,582)</u>	<u>(4,955)</u>
Leasehold improvements and equipment, net	<u>8,798</u>	<u>7,599</u>
<b>Total assets</b>	<b><u>\$ 243,250</u></b>	<b><u>\$ 238,062</u></b>

See accompanying notes to condensed consolidated financial statements.

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

	<b>June 30,</b>	<b>December 31,</b>
	<b>2015</b>	<b>2014</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 1,474	\$ 2,412
Accrued expenses	5,954	9,367
Current portion of unearned revenue	936	12,966
Current portion of deferred rent	85	84
Current portion of obligations under capital leases	31	35
Current portion of notes payable	556	157
Total current liabilities	<u>9,036</u>	<u>25,021</u>
<b>Long-term liabilities:</b>		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	450	941
Unearned revenue	809	1,085
Deferred rent	1,196	1,238
Total long-term liabilities	<u>8,455</u>	<u>9,264</u>
Total liabilities	<u>17,491</u>	<u>34,285</u>
<b>Stockholders' Equity:</b>		
Blank check preferred stock, \$0.01 par value: Authorized shares — 5,000,000 at June 30, 2015 and December 31, 2014; issued and outstanding shares — 0 at June 30, 2015 and December 31, 2014	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 at June 30, 2015 and December 31, 2014; issued 28,679,388 and 27,991,242 at June 30, 2015 and December 31, 2014, respectively, and outstanding 28,661,588 and 27,980,849 at June 30, 2015 and December 31, 2014, respectively	287	280
Additional paid-in capital	262,055	236,838
Treasury stock, at cost: 17,800 and 10,393 shares at June 30, 2015 and December 31, 2014, respectively	(551)	(222)
Accumulated deficit	(36,032)	(33,119)
Total stockholders' equity	<u>225,759</u>	<u>203,777</u>
Total liabilities and stockholders' equity	<u>\$ 243,250</u>	<u>\$ 238,062</u>

See accompanying notes to condensed consolidated financial statements.

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Grant revenue	\$ 3,280	\$ 212	\$ 12,929	\$ 546
Licensing and collaboration revenue	4,165	—	33,711	—
<b>Total operating revenues</b>	<b>7,445</b>	<b>212</b>	<b>46,640</b>	<b>546</b>
Operating expenses:				
Research and development	16,130	6,475	34,111	12,863
General and administrative	7,257	2,863	15,623	6,114
<b>Total operating expenses</b>	<b>23,387</b>	<b>9,338</b>	<b>49,734</b>	<b>18,977</b>
Loss from operations	(15,942)	(9,126)	(3,094)	(18,431)
Other income and expense:				
Miscellaneous expense	—	(50)	—	—
Interest income	26	21	43	45
Interest expense	(4)	(9)	(10)	(13)
<b>Other income (expense), net</b>	<b>22</b>	<b>(38)</b>	<b>33</b>	<b>32</b>
Loss before taxes	(15,920)	(9,164)	(3,061)	(18,399)
Income tax benefit	1,829	—	160	—
Net loss	\$ (14,091)	\$ (9,164)	\$ (2,901)	\$ (18,399)
Basic and diluted loss per share	\$ (0.49)	\$ (0.33)	\$ (0.10)	\$ (0.66)
Basic and diluted average shares outstanding	28,661,588	27,876,652	28,408,474	27,742,029

See accompanying notes to condensed consolidated financial statements.

**NewLink Genetics Corporation  
and Subsidiaries**  
**Condensed Consolidated Statements of Stockholders' Equity**  
**(unaudited)**  
**(In thousands, except share data)**

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	27,980,849	\$ 280	\$ 236,838	\$ (222)	\$ (33,119)	\$ 203,777
Share-based compensation	—	—	9,121	—	—	9,121
Exercise of stock options	333,508	4	2,164	—	—	2,168
Sale of shares under stock purchase plan	18,988	—	401	—	—	401
Issuance of common stock under the ATM Offering (net of offering costs of \$692)	329,402	3	13,531	—	—	13,534
Shares withheld for statutory tax withholding	(1,701)	—	—	(341)	—	(341)
Issuance of common stock from treasury	542	—	—	12	(12)	—
Net loss	—	—	—	—	(2,901)	(2,901)
Balance at June 30, 2015	<u>28,661,588</u>	<u>\$ 287</u>	<u>\$ 262,055</u>	<u>\$ (551)</u>	<u>\$ (36,032)</u>	<u>\$ 225,759</u>

See accompanying notes to condensed consolidated financial statements.

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

	<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (2,901)	\$ (18,399)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Share-based compensation	9,121	3,604
Depreciation and amortization	627	517
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses	(3,011)	327
State research and development credit receivable	(427)	(168)
Other receivables	(8,852)	1,167
Accounts payable and accrued expenses	(4,007)	16
Income taxes receivable	13,085	(125)
Unearned revenue	(12,305)	—
Deferred rent	(41)	(42)
Net cash used in operating activities	(8,711)	(13,103)
<b>Cash Flows From Investing Activities</b>		
Maturity of certificates of deposit	8,191	—
Purchase of equipment	(2,173)	(297)
Net cash provided by (used in) investing activities	6,018	(297)
<b>Cash Flows From Financing Activities</b>		
Issuance of common stock, net of offering costs	16,103	29,247
Repurchase of common stock	(341)	(182)
Principal payments on notes payable	(78)	(77)
Payments under capital lease obligations	(18)	(18)
Net cash provided by financing activities	15,666	28,970
Net increase in cash and cash equivalents	12,973	15,570
Cash and cash equivalents at beginning of period	190,404	61,291
Cash and cash equivalents at end of period	\$ 203,377	\$ 76,861
<b>Supplemental disclosure of cash flows information:</b>		
Cash paid for interest	\$ 10	\$ 13
Cash paid for taxes	255	—
<b>Noncash financing and investing activities:</b>		
Purchased leasehold improvements and equipment in accounts payable	3	89

See accompanying notes to condensed consolidated financial statements.

**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

## **1. Description of Business**

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 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. In 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 had a net loss of \$14.1 million and \$2.9 million for the three and six months ending June 30, 2015, respectively. For the six months ended June 30, 2015, the Company's loss was lower than the three-month period ending June 30, 2015 primarily as a result of earning a milestone payment during the first quarter of 2015 pursuant to a license and collaboration agreement the Company entered into with Merck, Sharpe and Dohme Corp., or Merck, in 2014.

The accompanying financial statements as of June 30, 2015 and for the three and six months then ended 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, and raised an additional \$58.7 million in net proceeds from the ATM Offering prior to June 30, 2015. In connection with two license and collaboration agreements the Company entered into during 2014, the Company received a nonrefundable upfront cash payment of \$150.0 million from Genentech Inc., a member of the Roche Group, or Genentech, in 2014, and a nonrefundable upfront cash payment of \$30.0 million from Merck in 2014, as well as an additional milestone payment of \$20.0 million from Merck in February 2015. 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. Basis of Presentation**

The interim financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), without audit, and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim condensed financial information.

Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2014, included in the Company's Annual Report on Form 10-K. There were no significant changes in the Company's accounting policies since the end of fiscal 2014. The financial results for any interim period are not necessarily indicative of financial results for the full year.

## **3. Significant Accounting Policies**

### ***(a) Use of Estimates***

The preparation of consolidated financial statements in conformity with 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



**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

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) Financial Instruments and Concentrations of Credit Risk**

Cash and cash equivalents, certificates of deposit, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The fair value and carrying value of notes payable and capital lease obligations was \$1.0 million and \$1.1 million as of June 30, 2015 and December 31, 2014, respectively, and was determined using Level 2 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 certificates of deposit.

**(d) 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, 2018; however, early adoption at January 1, 2017, is 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.

**4. Long-Term Debt**

***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 March 31, 2016.

The project calls for the Company to create or retain at least 150 full-time positions located in Ames, Iowa. In March 2015, the City of Ames granted a one-year extension for the deadline to obtain the required number of jobs to March 10, 2016. The agreement required 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, which requirement was met prior to the deadline of 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 June 30, 2015, \$397,000 of the total \$400,000 forgivable loan was advanced to the Company. As of June 30, 2015, the Company has created or retained at least 150 full-time positions in Ames, Iowa. 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 an exclusive worldwide collaboration and license agreement with Genentech, or the Genentech Agreement, for the development and commercialization of GDC-0919, one of the Company's clinical stage IDO pathway inhibitors. The parties also entered into a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors to be developed and commercialized under this agreement. Under the terms of the Genentech Agreement, the

**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

Company received a nonrefundable upfront cash payment of \$150.0 million from Genentech in 2014 and is eligible to receive additional payments of over \$1.0 billion upon achieving certain GDC-0919 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.

For the three and six months ended June 30, 2015 the Company recognized revenue under the Genentech Agreement of \$2.7 million and \$12.2 million, respectively, associated with license and manufacturing technology transfer deliverables, which were completed in their entirety during the quarter. In accordance with the Company's continuing performance obligation, \$1.6 million of the \$150.0 million upfront payment is being deferred and recognized in future years. The upfront payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

***Merck Sharp & Dohme Corp.***

In November 2014, the Company entered into a licensing and collaboration agreement with Merck, or the Merck Agreement, to develop, manufacture and commercialize rVSV-EBOV (V920), an Ebola vaccine the Company licensed from the Public Health Agency of Canada, or PHAC. Under the terms of the Merck Agreement, the Company granted Merck an exclusive, royalty-bearing license to rVSV-EBOV (V920) and related technology. Accordingly, the accounting for the transaction commenced in the fourth quarter of 2014. Under the Merck Agreement, the Company received a \$30.0 million non-refundable, upfront payment in December 2014, and a one-time \$20.0 million non-refundable milestone payment in February 2015 upon the initiation of the pivotal clinical trial using the current rVSV-EBOV (V920) vaccine product as one arm of the trial. In addition, the Company 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 (V920) 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 (V920) and any other rVSV-based viral hemorrhagic fever vaccine product candidates in order to create a marketable product safe for human use.

For the six months ended June 30, 2015 the Company recognized revenue under the Merck Agreement of \$20.0 million associated with the one-time non-refundable milestone payment. For the three and six months ended June 30, 2015, the Company recognized revenues of \$36,000 and \$134,000, respectively, associated with the remaining deliverables. In accordance with the Company's continuing performance obligations, \$98,000 of the \$30.0 million upfront payment is being deferred and recognized in future years. The upfront payment provides no general right of return for any non-contingent deliverable, and no portion of any revenue recognized is refundable.

## **6. Common Stock Equity Incentive Plan**

### ***2009 Equity Incentive Plan***

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan, or the 2000 Plan, and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or 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, the Company 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 Board of Directors, advisors, and consultants to the Company. As of June 30, 2015, there were 7,192,547 shares of common stock authorized for the 2009 Plan and 927,421 shares remained available for issuance.

On May 15, 2010 and January 7, 2011, stockholders authorized increases of 1,238,095 and 714,286 shares of common stock available for issuance under the 2009 Plan, respectively. On January 1, 2013, 2014 and 2015, an additional 838,375, 1,066,340 and 1,119,255 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan, respectively, 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

**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

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.

**2010 Non-Employee Directors' Stock Award Plan**

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan, or 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 shares reserved for future issuance under the Directors' Plan. As of June 30, 2015, 131,632 shares remained available for issuance under the plan.

**2010 Employee Stock Purchase Plan**

Under the terms of the Company's 2010 Employee Stock Purchase Plan, or 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 shares reserved for future issuance under the 2010 Purchase Plan. As of June 30, 2015, 252,652 shares remained available for issuance under the plan.

**Share-based Compensation**

Share-based compensation expense for the three and six months ended June 30, 2015 and June 30, 2014 was \$5.9 million, and \$9.1 million, \$1.5 million, and \$3.6 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to related tax benefits of \$0 and \$0, respectively, for the three and six months ended June 30, 2015 and 2014. During the three months ended June 30, 2015, there was \$2.4 million in share-based compensation expense that was classified as research and development expense resulting from the vesting in full of an employee's options upon the employee's departure from the Company.

As of June 30, 2015, the total compensation cost related to nonvested option awards not yet recognized was \$30.8 million and the weighted-average period over which it is expected to be recognized is 3.2 years.

**Stock Options**

The following table summarizes the stock option activity for the six months ended June 30, 2015:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	5,098,311	\$ 9.46	
Options granted	829,085	43.27	
Options exercised	(301,148)	7.19	
Options forfeited	(29,431)	40.05	
Options expired	—	—	
Outstanding at end of period	5,596,817	\$ 14.22	6.3
Options exercisable at end of period	3,815,242	\$ 6.91	5.1

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**(unaudited)**

The following table summarizes the range of assumptions used to estimate the fair value of stock options issued during the six months ended June 30, 2015:

Risk-free interest rate	1.5%-2.0%
Expected dividend yield	—%
Expected volatility	62.5%-65.6%
Expected term (in years)	5.9-7.0
Weighted-average grant-date fair value per share	\$26.65

The intrinsic value of options exercised during the six months ended June 30, 2015 was \$11.8 million. The fair value of awards vested during the six months ended June 30, 2015 was \$5.0 million. The fair value of options vested for the six months ended June 30, 2015 includes the fair value of options with accelerated vesting as a result of an employee's departure from the Company of \$2.8 million.

### **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 classified as equity 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.

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 grants made in 2015. During the six months ended June 30, 2015 and 2014, there were 130,610 and 133,420 shares of restricted stock granted, respectively. These restricted stock grants had a weighted average fair value (per share) at date of grant of \$43.67 and \$21.71, respectively. At June 30, 2015 and 2014, there were 238,249 and 93,420 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 June 30, 2015 and changes during the six months ended June 30, 2015 is as follows:

	<b>Restricted Stock</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested at beginning of period	153,509	\$ 23.63
Granted	130,610	43.67
Vested	(38,070)	21.62
Forfeited/cancelled	(7,800)	43.65
Unvested restricted stock at end of period	<u>238,249</u>	<u>\$ 34.28</u>

As of June 30, 2015, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately \$7.1 million and is expected to be recognized over a weighted-average period of 3.3 years. The grant date fair value of awards granted during the three months ended June 30, 2015 was \$5.7 million. The fair value of awards vested during the six months ended June 30, 2015 was \$1.7 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.

**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

## **7. Income Taxes**

For the three and six months ended June 30, 2015, the Company recorded an income tax benefit of \$1.8 million and \$160,000 respectively. For the three and six months ended June 30, 2014 the Company incurred no income tax expense. The income tax benefit for the three and six months ended June 30, 2015, differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the changes in the valuation allowance for deferred taxes, the potential to carry back losses and orphan drug credits to 2014, and other permanent differences. Income tax expense for the three and six months ended June 30, 2014 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the changes in the valuation allowance for deferred taxes.

The valuation allowance for deferred tax assets as of June 30, 2015 and December 31, 2014 was \$9.5 million and \$7.1 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of June 30, 2015 and December 31, 2014, due to the uncertainty of future recoverability.

As of June 30, 2015, we had federal net operating loss carryforwards of \$2.5 million and federal research and orphan drug credit carryforwards of \$1.9 million. For the year ended December 31, 2014, we utilized \$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 from 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. For the year ended December 31, 2014, 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 BPS. Additional ownership changes may have occurred subsequent to December 31, 2014 and 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 its 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.

For the six months ended June 30, 2015, the Company received a \$13.5 million refund payment from the IRS for overpayment of U.S. federal income taxes paid in 2014.

## **8. Net Loss per Common Share**

Basic net loss per share is based upon the weighted-average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average potentially dilutive common shares outstanding during the period when the effect is dilutive.

**NewLink Genetics Corporation and Subsidiaries**  
**Notes to Condensed Consolidated Financial Statements**  
**(unaudited)**

The following table presents the computation of basic and diluted net loss per common share (in thousands, except share and per share data):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Historical net loss per share</b>				
Net loss attributable to common stockholders	\$ (14,091)	\$ (9,164)	\$ (2,901)	\$ (18,399)
Basic and diluted weighted-average shares outstanding	28,661,588	27,876,652	28,408,474	27,742,029
Basic and diluted net loss per share	\$ (0.49)	\$ (0.33)	\$ (0.10)	\$ (0.66)

As of June 30, 2015, potentially dilutive stock options to purchase 912,736 shares of common stock and restricted stock awards representing 25,000 shares of common stock which had market prices at their award dates that were greater than the average market price, were excluded from our calculation of diluted net loss per share because to do so would be anti-dilutive. As of June 30, 2015 and 2014, respectively, 5,596,817 and 4,804,850 common equivalent shares of potentially dilutive securities were not included in the calculation of diluted loss per common share because to do so would be anti-dilutive.

## 9. Commitments and Contingencies

From time to time, claims are asserted against the Company arising in the ordinary course of business. In the opinion of management, liabilities, if any, arising from existing claims are not expected to have a material effect on the Company's earnings, financial position, or liquidity.

## 10. Subsequent Events

The Company announced on July 31, 2015 that the international partnership studying the rVSV-EBOV (V920) vaccine candidate in Guinea has released interim data suggesting that it is effective against Ebola in a large clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about ten days of administration to a person without the infection.

The rVSV-EBOV (V920) vaccine candidate was originally developed by the PHAC, and was subsequently licensed to BPS. In late 2014, Merck licensed the vaccine from the Company to apply Merck's vaccine expertise to help accelerate the development of this promising candidate. Merck is now responsible for research, development and manufacturing of the vaccine candidate pursuant to the Merck Agreement.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our plans to develop and commercialize our product candidates; our ongoing and planned preclinical studies and clinical trials, including the timing for completion of enrollment and outcome of our Phase 3 clinical trial for our algenpantucel-L cancer immuno-oncology product candidate; the timing of release of the results of interim analyses or other data from ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; 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 described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2014. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. 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.*

*The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.*

### 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 immuno-oncology product candidates intended to treat a wide range of oncology indications. 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. We believe that our immuno-oncology technologies have the potential to lead to multiple product candidates, targeting a wide range of oncology indications that could 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 (V920) vaccine product candidate for the Ebola virus.

Our most advanced program, algenpantucel-L, 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 surgically resected pancreatic cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or the 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 potential to improve both disease-free and overall survival. Algenpantucel-L has received Fast Track and Orphan Drug designations from the FDA and Orphan Medicinal Product designation 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 the adjuvant treatment of 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. The second interim analysis was completed during the second quarter of 2015 following 333 deaths, which had occurred prior to February 26, 2015. For the second interim analysis, the DSMC reviewed available patient data and recommended the study proceed without modification to final analysis. The Company has announced that concurrently with the second interim analysis a Kaplan-Meier estimation of overall median survival calculated from the same data set determined that the estimated

blended median overall survival in the trial from the time of randomization was 28.5 months for all patients. Median time from surgery to randomization was approximately 1.5 months. Therefore median survival from surgery was estimated to be approximately 30 months for all patients in our study. The study is powered to show an improvement in overall survival after the planned 442 events.

Our additional HyperAcute Immunotherapy product candidates in clinical development include tergenpumatulcel-L or HyperAcute Lung, dorgenmeltucel-L or HyperAcute Melanoma, and products for other potential indications. To date, our HyperAcute Immunotherapy 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 been shown to be generally well tolerated with limited grade 3/4 adverse events.

Our HyperAcute Immunotherapy platform consists of novel biologic products designed to stimulate the patient's immune system to recognize and attack cancer cells. HyperAcute Immunotherapy 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 human immune response against cancer cells. The objective of HyperAcute Immunotherapy 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 Immunotherapy product candidates have the potential to result in the stimulation of a robust immune response.

In addition to our HyperAcute Immunotherapy platform, we have an active drug discovery and clinical development program focused on the IDO (indoleamine-2,3-dioxygenase) and TDO (tryptophan-2,3-dioxygenase) pathways. Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that we believe have the potential to be breakthrough approaches to cancer therapy. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of GDC-0919, 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 \$150.0 million in November 2014. 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 double-digit royalties on potential commercial sales of multiple products by Genentech. Genentech will fund future research, development, manufacturing and commercialization costs. Genentech will also provide us research funding for support of the research collaboration. We will continue to pursue development activities associated with GDC-0919 in combination with our novel HyperAcute Immunotherapy platform. We retain the option for co-promotion rights for GDC-0919 and potential next-generation IDO/TDO compounds in the U.S.

Our proprietary IDO pathway inhibitor, indoximod, is in multiple Phase 1 and Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic and brain cancers as well as melanoma.

Our small molecule IDO pathway inhibitor drug candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1 and PD-L1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumor immune escape. Recent studies have demonstrated 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, whereby this pathway promotes peripheral tolerance to tumor associated antigens (TAAs). When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system. We have a number of active programs directed at synthesizing inhibitors that are potential anti-cancer compounds and that could function individually or in combination with IDO inhibition.

Our infectious disease business 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.

Our primary program is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses. The rVSV-EBOV (V920) vaccine candidate was originally developed by the Public Health Agency of Canada and 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, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our rVSV-EBOV (V920) (Ebola) vaccine product candidate. Under the Merck



Agreement, we received an upfront payment of \$30 million in October 2014, and in February 2015 we received a milestone payment of \$20.0 million. 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. The Company announced on July 31, 2015 that the international partnership studying the rVSV-EBOV (V920) vaccine candidate in Guinea has released interim data suggesting that it is effective against Ebola in a large clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-EBOV (V920) product candidate will continue to be studied in clinical trials.

We had a net loss of \$14.1 million and \$2.9 million for the three and six months ended June 30, 2015, respectively. For the six-month period ending June 30, 2015, our loss was lower than the loss for the three-month period ending June 30, 2015 primarily as a result of earning a \$20.0 million milestone payment from Merck in February 2015. We did not have any similar transactions in the three-month period ending June 30, 2015, nor do we expect any similar transactions in the remainder of 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.

### **Critical Accounting Policies and Significant Judgments and Estimates**

We have prepared our financial statements in accordance with United States generally accepted accounting policies, which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. As such, to understand our financial statements, it is important to understand our critical accounting policies. This language is helpful in fully explaining the effects of accounting policies on the financial statements, which is a requirement of Regulation S-K. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

Our Annual Report on Form 10-K for the year ended December 31, 2014, discusses our most critical accounting policies. Since December 31, 2014, there have been no material changes in the critical accounting policies discussed in the 2014 Annual Report.

### **Results of Operations**

#### ***Comparison of the Three Months Ended June 30, 2015 and 2014***

*Revenues.* Revenues for the three months ended June 30, 2015 were \$7.4 million, increasing from \$212,000 for the same period in 2014. The increase in revenue of \$7.2 million was due to an increase of \$4.1 million in licensing and collaboration revenue earned under our licensing and collaboration agreements and a \$3.1 million increase in grant revenue earned under various government contracts.

*Research and Development Expenses.* Research and development expenses for the three months ended June 30, 2015 were \$16.1 million, increasing from \$6.5 million for the same period in 2014. Of the \$9.6 million increase, \$4.5 million was due to costs related to the Ebola vaccine product candidate, outside clinical and other expenses, contract development costs for

GDC-0919, contract manufacturing costs for indoximod, consulting fees, and direct development expenses for our clinical trial activities. There was also a \$4.2 million increase in personnel-related expenses due to increased staffing levels, compensation increases, which includes \$2.4 million in share-based compensation expense recognized in connection with the departure of an executive, and a \$900,000 increase in equipment and supplies.

*General and Administrative Expenses.* General and administrative expenses for the three months ended June 30, 2015 were \$7.3 million, increasing from \$2.9 million for the same period in 2014. The \$4.4 million increase was due to a \$2.8 million increase in personnel-related expenses due to increased staffing levels, share-based compensation expense, and compensation increases, accompanied by a \$1.5 million increase in consulting, legal and licensing fees, and a \$100,000 increase in equipment and supplies.

*Income Tax Benefit.* The income tax benefit for the three months ended June 30, 2015 was \$1.8 million, compared to \$0 for the same period in 2014. The change is primarily due to our ability to carry tax losses and the orphan drug credit back to 2014.

*Net Loss.* The net loss for the three months ended June 30, 2015 was \$14.1 million compared to \$9.2 million for the same period in 2014. The \$4.9 million increase in the net loss was due to a \$14.0 million increase in operating expenses offset by a \$7.2 million increase in revenues and a \$1.8 million income tax benefit as discussed above. The basic and diluted weighted average common shares outstanding for the second quarter of 2015 were 28,661,588, resulting in a loss per share of \$0.49, as compared to 27,876,652 and a \$0.33 loss per share for the second quarter of 2014.

#### **Comparison of the Six Months Ended June 30, 2015 and 2014**

*Revenues.* Revenues for the six months ended June 30, 2015 were \$46.6 million, increasing from \$546,000 for the same period in 2014. The increase in revenue of \$46.1 million was due to an increase of \$33.7 million in licensing and collaboration revenue, primarily due to a one-time \$20.0 million non-refundable milestone payment in February 2015, and a \$12.4 million increase in grant revenue under various government contracts.

*Research and Development Expenses.* Research and development expenses for the six months ended June 30, 2015 were \$34.1 million, increasing from \$12.9 million for the same period in 2014. Of the \$21.2 million increase, \$14.3 million was due to expenses related to the Ebola vaccine product candidate, outside clinical and other expenses, including contract manufacturing costs for indoximod, consulting fees, and direct development expenses for our clinical trial activities. There was also a \$5.5 million increase in personnel-related expenses due to increased staffing levels and compensation increases, which includes \$2.4 million in share-based compensation expense recognized in connection with the departure of an executive and a \$1.4 million increase in equipment and supplies.

*General and Administrative Expenses.* General and administrative expenses for the six months ended June 30, 2015 were \$15.6 million, increasing from \$6.1 million for the same period in 2014. The \$9.5 million increase was due to a \$4.9 million increase in consulting, legal and licensing fees, accompanied by a \$4.4 million increase in personnel-related expenses due to increased staffing levels, share-based compensation expense, and compensation increases and a \$200,000 increase in equipment and supplies.

*Income Tax Expense.* Income tax expense for the six months ended June 30, 2015 was \$160,000, compared to \$0 for the same period in 2014. The difference is primarily due to our ability to carry tax losses and the orphan drug credit back to 2014.

*Net Loss.* The net loss for the six months ended June 30, 2015 was \$2.9 million, compared to \$18.4 million for the same period in 2014. The \$15.5 million decrease was due to the changes in revenue earned, research and development and general and administrative expenses and income tax expense discussed above. The basic and diluted weighted-average common shares outstanding for the six months ended June 30, 2015 were 28,408,474, resulting in a loss per share of \$0.10, as compared to 27,742,029 and a \$0.66 loss per share for the six months ended June 30, 2014.

#### **Liquidity and Capital Resources**

We raised an aggregate of \$58.9 million in equity capital prior to our IPO, at which time all of our then-outstanding preferred stock converted to common stock. We raised net proceeds of \$37.6 million from our IPO. In the years following our IPO, we raised \$0 in 2012, net proceeds of \$49.0 million in a follow on offering in 2013, and we have raised an additional \$58.7 million in net proceeds from the ATM Offering through June 30, 2015 (\$17.5 million in 2013, \$27.7 million in 2014, and \$13.6 million year to date in 2015).

In October 2014, we received an upfront payment of \$150.0 million under the Genentech Agreement, and an upfront payment of \$30 million in November 2014 as well as a \$20.0 million milestone payment in February 2015 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 and Cash Equivalents**  
(in thousands)

	Six Months Ended June 30,	
	2015	2014
Net cash used in operating activities	\$ (8,711)	\$ (13,103)
Net cash provided by (used in) investing activities	6,018	(297)
Net cash provided by financing activities	15,666	28,970
Net increase in cash and cash equivalents	\$ 12,973	\$ 15,570

For the six months ended June 30, 2015 and 2014, we used cash of \$8.7 million and \$13.1 million, respectively, for our operating activities. For the six months ended June 30, 2015, the sources and uses of cash in this period primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. The net loss for this period was primarily due to an increase in licensing and grant revenue, offset by increased operating expense.

For the six months ended June 30, 2015 and 2014, our investing activities provided cash of \$6.0 million, and used cash of \$297,000, respectively. The cash provided by investing activities in the six months ended June 30, 2015 was due to maturity of certificates of deposit for \$8.2 million offset by \$2.2 million in purchases of property and equipment. The cash used by investing activities in the six months ended June 30, 2014 was due to \$297,000 in purchases of property and equipment.

For the six months ended June 30, 2015 and 2014, our financing activities provided \$15.7 million and \$29.0 million, respectively. The cash provided by financing activities in the six months ended June 30, 2015 was primarily due to the sale and issuance of common stock for net proceeds of \$16.1 million, offset by repurchase of common stock of \$341,000 and net payments on long-term obligations and notes payable of \$96,000. The cash provided by financing activities in the six months ended June 30, 2014 was primarily due to the sale and issuance of common stock for net proceeds of \$29.2 million, offset by the repurchase of common stock of \$182,000 and net payments on long-term obligations of \$95,000.

**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 stockholders. 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 determine 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 our 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;
- the potential requirement 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***

There are no material changes to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

### **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.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk related to changes in interest rates. As of June 30, 2015 and December 31, 2014, we had cash and cash equivalents and certificates of deposit of \$207.6 million and \$202.8 million, respectively, consisting of bank certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in certificates of deposit. 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.

Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial impact on our financial statements.

## **ITEM 4. 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 June 30, 2015. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2015, 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 chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### 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 surgically resected pancreatic cancer. If we fail to complete clinical trials, fail to demonstrate safety and efficacy in those 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 that 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 Immunotherapy 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 Immunotherapy 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 large-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 surgically resected 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 adjuvant treatment of patients with surgically resected 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 of 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 certain 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, and clinical trials for, competing therapies;
- 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 any Ebola vaccine product candidate 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 Practice, 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 Practice, 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 Immunotherapy product candidates, indoximod and other product candidates could take significantly longer 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 their commercialization.

***Some of our product candidates have been studied, 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.***

Indoximod, our proprietary IDO pathway inhibitor product candidate, has been studied in two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying indoximod in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L (HyperAcute Melanoma) 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 can 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 Immunotherapy product candidates, indoximod, GDC-0919, 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 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 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 immuno-oncology 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 GDC-0919, and we entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. If GDC-0919 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 GDC-0919 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 GDC-0919 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. 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 who 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 granted WuXi AppTec Inc., or 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 (the "WuXi Agreement"). We will incur significant expense under the WuXi Agreement or under similar commercial manufacturing arrangements, and our commercial manufacturing programs 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 such other manufacturers, 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 other manufacturers 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 such other manufacturers may encounter unforeseen difficulties in attempting to manufacture biological materials related to algenpantucel-L at a larger scale than we have previously attempted;
- other manufacturers 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 surgically resected pancreatic cancer, or any subset of such patients, which would not relieve our obligation for certain costs under the WuXi Agreement or other such agreements, if any.

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 our Company, 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 development efforts of our Ebola vaccine product candidate.***

We have entered into certain 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 of 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, a circumstance that 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 Immunotherapy product candidates, indoximod, GDC-0919 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 HyperAcute Immunotherapy clinical product candidates. 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 HyperAcute Immunotherapy clinical product candidates 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 HyperAcute Immunotherapy 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 HyperAcute Immunotherapy 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 HyperAcute Immunotherapy manufacturing facility would have a significant negative impact on our ability to manufacture HyperAcute Immunotherapy 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 mycoplasma 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 in our ability to produce material for clinical trials, or if approved, products for commercial sale 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 \$12.1 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 or 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 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 profitable fiscal year ended December 31, 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 upfront payments under the Genentech Agreement and 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 GDC-0919 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 \$35.8 million as of June 30, 2015. 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 2016. 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 biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or partner with collaborators in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. The competitors of which we are aware that have initiated a Phase 3 study or have obtained marketing approval for a potentially competitive drug to our lead product candidate, algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer, include Astra-Zeneca, Celgene Corporation, Incyte Corporation, Merrimack Pharmaceuticals, and Threshold Pharmaceuticals. Our competitors in the field of immuno-oncology and cancer vaccines include AdaptImmune LLC, Aduro Biotech, Advaxis, Inc., AstraZeneca PLC, Bristol Myers-Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immune Design Corp., Incyte Corporation, Merck & Co., Inc., Merrimack Pharmaceuticals, Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd, and Sanofi SA, among others. Many other companies are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our drug candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of drug candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. If we obtain regulatory approval and launch commercial sales of our drug candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both in the U.S. and outside of the U.S.

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, indoximod, GDC-0919 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 immuno-oncology products 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 GDC-0919 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 with 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, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to 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 if 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 GDC-0919 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 or required financial resources, efforts or 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 the 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, disputes that may be 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 has the right to terminate the Genentech Agreement for any reason after October 16, 2016 and Merck has the right to terminate the Merck Agreement for any reason after 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 may 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 which 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 them.

***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 of 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 as 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 Quarterly Report on Form 10-Q 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 success or failure, 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 June 30, 2015, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 50.6% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after March 31, 2015. 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 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 that 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.

***The holdings of 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 subsidiaries.

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 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 1. LEGAL PROCEEDINGS**

None.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**Recent Sales of Unregistered Securities**

None.

**Use of Proceeds**

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. Mine Safety Disclosures**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The exhibits listed in the Index to Exhibits (following the signatures page of this Quarterly Report) are filed with, or incorporated by reference in, this Quarterly Report.

## 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: August 6, 2015

By:           /s/ John B. Henneman, III

John B. Henneman, III

Chief Financial Officer and Secretary

(Principal Financial Officer)

Date: August 6, 2015



The following exhibits are filed with this form 10-Q 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 hereof				
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	
10.1	† 2010 Non-Employee Directors' Stock Award Plan, as amended				X
10.2	† Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan				X
10.3	† Separation and Release Agreement between the Company and W. Jay Ramsey, dated as of May 22, 2015				X
31.1	Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2	Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1	# Section 1350 Certification				X
101.INS	‡ XBRL Instance Document				X
101.SCH	‡ XBRL Taxonomy Extension Schema Document				X
101.CAL	‡ XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	‡ XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	‡ XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	‡ XBRL Taxonomy Extension Presentation Linkbase Document				X

† Indicates management contract or compensatory plan

# The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q 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-Q, irrespective of any general incorporation language contained in such filing.

‡ Filed herewith electronically.

**NewLink Genetics Corporation**  
**2010 Non-Employee Directors' Stock Award Plan**

**Adopted by the Board of Directors: October 29, 2010**

**Approved by the Stockholders: January 7, 2011**

**Amended by the Board of Directors: July 1, 2011**

**Amended by the Board of Directors: January 14, 2013**

**Amended by the Board of Directors: February 22, 2013**

**Approved by the Stockholders: May 9, 2013**

**Amended by the Board of Directors: April 30, 2014**

**Amended by the Board of Directors: April 30, 2015**

**1. General.**

(a) **Eligible Stock Award Recipients.** The persons eligible to receive Stock Awards are the Non-Employee Directors of the Company.

(b) **Available Stock Awards.** The Plan provides for the grant of the following Stock Awards: (i) Nonstatutory Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, and (v) Other Stock Awards.

(c) **Purpose.** The Company, by means of the Plan, seeks to retain the services of its Non-Employee Directors, to secure and retain the services of new Non-Employee Directors and to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate by giving them an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

**2. Administration.**

(a) **Administration by Board.** The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) **Powers of Board.** The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) With respect to Stock Awards issued pursuant to Sections 5(a) and 5(b), to determine the provisions of each Stock Award to the extent not specified in the Plan.

(ii) With respect to Stock Awards issued pursuant to Section 5(d), to determine from time to time (A) which of the persons eligible under the Plan shall be granted Stock Awards; (B) when and how each Stock Award shall be granted; (C) what type or combination of types of Stock Awards shall be granted; (D) the provisions of each Stock Award granted (which need not be identical), including the time or times when a person shall be permitted to receive cash or Common Stock pursuant to a Stock Award; (E) the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person; and (F) the Fair Market Value applicable to a Stock Award.

(iii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan or Stock Award fully effective.

(iv) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to certain nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Stock Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. However, except as provided in Section 10(a) relating to Capitalization Adjustments, to the extent required by applicable law or listing requirements,

stockholder approval shall be required for any amendment of the Plan that either (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Stock Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (D) materially extends the term of the Plan, or (E) expands the types of Stock Awards available for issuance under the Plan. Except as provided above, rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(v) To effect, at any time and from time to time, with the consent of any adversely affected Participant, (A) the reduction of the exercise price (or strike price) of any outstanding Option or SAR under the Plan; (B) the cancellation of any outstanding Option or SAR under the Plan and the grant in substitution therefor of (1) a new Option or SAR under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, (2) a Restricted Stock Award, (3) a Restricted Stock Unit Award, (4) an Other Stock Award, (5) cash and/or (6) other valuable consideration (as determined by the Board, in its sole discretion); or (C) any other action that is treated as a repricing under generally accepted accounting principles.

(vi) To amend the Plan or a Stock Award as provided in Section 11.

(vii) To terminate or suspend the Plan as provided in Section 12.

(viii) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan.

(c) **Delegation to Committee.**

(i) **General.** The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated.

(ii) **Rule 16b-3 Compliance.** The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) **Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

3. **Shares Subject to the Plan.**

(a) **Share Reserve.** Subject to Section 10(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock of the Company that may be issued pursuant to Stock Awards after the Effective Date shall not exceed four hundred thousand (400,000) shares. For clarity, the limitation in this Section 3(a) is a limitation in the number of shares of Common Stock that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 8(a). Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, NASDAQ Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable stock exchange rules, and such issuance shall not reduce the number of shares available for issuance under the Plan. Furthermore, if a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement shall not

reduce (or otherwise offset) the number of shares Common Stock that may be available for issuance under the Plan.

(b) **Reversion of Shares to the Share Reserve.** If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited shall revert to and again become available for issuance under the Plan. Any shares reacquired, withheld or not issued by the Company pursuant to Section 9(e) or as consideration for the exercise of a Stock Award shall again become available for issuance under the Plan. For the avoidance of doubt, if an appreciation distribution in respect of a Stock Appreciation Right is paid in shares of Common Stock, the number of shares subject to the Stock Award that are not delivered to the Participant shall remain available for subsequent issuance under the Plan.

(c) **Source of Shares.** The stock issuable under the Plan shall be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

#### 4. **Eligibility.**

The Initial and Annual Grants as set forth in Sections 5(a) and 5(b) automatically shall be granted under the Plan to all Non-Employee Directors who meet the specified criteria. Stock Awards may also be granted to Non-Employee Directors as discretionary grants as set forth in Section 5(d).

#### 5. **Non-Discretionary and Discretionary Grants.**

##### (a) **Initial Grants.**

(i) Prior to January 14, 2013, without any further action of the Board, each person who after the IPO Date was elected or appointed for the first time to be a Non-Employee Director automatically was granted an Option to purchase 11,904 shares of Common Stock on the date of his or her initial election or appointment to be a Non-Employee Director on the terms and conditions set forth herein.

(ii) Beginning on January 14, 2013 and prior to April 30, 2014, without any further action of the Board, each person who was elected or appointed for the first time to be a Non-Employee Director automatically was, upon the date of his or her initial election or appointment to be a Non-Employee Director, granted an Option to purchase 20,000 shares of Common Stock on the terms and conditions set forth herein.

(iii) Beginning on April 30, 2014, and prior to April 30, 2015, without any further action of the Board, each person who is elected or appointed for the first time to be a Non-Employee Director automatically shall, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted an Option and a Restricted Stock Unit Award that together have a total value on the date of grant equal to \$500,000 on the terms and conditions set forth herein. The number of shares subject to each Stock Award will be determined as follows:

(1) The number of shares subject to the Option will be equal to (i) 75% of \$500,000, (ii) divided by the per share grant date fair value that will be used for reporting the compensation expense associated with the Option under applicable accounting guidance.

(2) The number of shares subject to the Restricted Stock Unit Award will be equal to (i) 25% of \$500,000, (ii) divided by the Fair Market Value of the Common Stock on the date of grant.

(iv) Beginning on April 30, 2015, without any further action of the Board, each person who is elected or appointed for the first time to be a Non-Employee Director automatically shall, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted an Option and a Restricted Stock Unit Award that together have a total value on the date of grant equal to \$500,000 on the terms and conditions set forth herein. The number of shares subject to each Stock Award will be determined as follows:

(1) The number of shares subject to the Option will be equal to (i) 65% of \$500,000, (ii) divided by the per share grant date fair value that will be used for reporting the compensation expense associated with the Option under applicable accounting guidance.

(2) The number of shares subject to the Restricted Stock Unit Award will be equal to (i) 35% of \$500,000, (ii) divided by the Fair Market Value of the Common Stock on the date of grant.

(b) **Annual Grants.**

(i) Prior to January 14, 2013, without any further action of the Board, on the date of each Annual Meeting, commencing with the first Annual Meeting following the IPO Date, each person who was then a Non-Employee Director automatically was granted an Option to purchase, on the terms and conditions set forth herein:

(1) 7,142 shares of Common Stock; plus

(2) 3,571 shares of Common Stock for Non-Employee Directors who were serving as the chair of the Audit, Compensation or Nominating and Corporate Governance Committee, or as Lead Independent Director on the date of grant; plus

(3) 2,380 shares of Common Stock for Non-Employee Directors who were serving (but not as the chair) on the Audit, Compensation or Nominating and Corporate Governance Committee on the date of grant.

(ii) Beginning on January 14, 2013 and prior to April 30, 2014, without any further action of the Board: (x) on the date of each Annual Meeting, commencing with the Annual Meeting held in 2013, each person who was a Non-Employee Director immediately after such meeting of shareholders automatically was granted an Option to purchase 12,000 shares of common stock on the terms and conditions set forth herein, and (y) any person elected as or appointed to become a Non-Employee Director at a time other than at the Annual Meeting, upon the date of such election or appointment, was granted an Option to purchase the number of shares determined by multiplying 12,000 by a fraction, the numerator of which was the number of days between the date of such election and the date which was the first anniversary of the date of the last preceding Annual Meeting, and the denominator of which was 365.

(iii) Beginning on April 30, 2014, and prior to April 30, 2015, without any further action of the Board:

(1) On the date of each Annual Meeting, commencing with the Annual Meeting held in 2014, each person who is a Non-Employee Director immediately after such meeting of shareholders automatically shall be granted an Option and a Restricted Stock Unit Award that together have a total value on the date of grant equal to \$250,000 on the terms and conditions set forth herein. The number of shares subject to each Stock Award will be determined as follows:

a. The number of shares subject to the Option will be equal to (i) 75% of \$250,000, (ii) divided by the per share grant date fair value that will be used for reporting the compensation expense associated with the Option under applicable accounting guidance.

b. The number of shares subject to the Restricted Stock Unit Award will be equal to (i) 25% of \$250,000, (ii) divided by the Fair Market Value of the Common Stock on the date of grant.

(2) Any person elected as or appointed to become a Non-Employee Director at a time other than at the Annual Meeting, upon the date of such election or appointment, will be granted:

a. an Option to purchase the number of shares determined by multiplying the number of shares as determined pursuant to 5(b)(iii)(1)(a) by a fraction, the numerator of which will be the number of days between the date of such election and the date which is the first anniversary of the date of the last preceding Annual Meeting, and the denominator of which will be 365, and

b. a Restricted Stock Unit Award for the number of shares determined by multiplying the number of shares as determined pursuant to 5(b)(iii)(1)(b) by a fraction, the numerator of which will be the number of days between the date of such election and the date which is the first anniversary of the date of the last preceding Annual Meeting, and the denominator of which will be 365.

(iv) Beginning on April 30, 2015, without any further action of the Board:

(1) On the date of each Annual Meeting, commencing with the Annual Meeting held in 2014, each person who is a Non-Employee Director immediately after such meeting of shareholders automatically shall be granted an Option and a Restricted Stock Unit Award that together have a total value

on the date of grant equal to \$250,000 on the terms and conditions set forth herein. The number of shares subject to each Stock Award will be determined as follows:

a. The number of shares subject to the Option will be equal to (i) 65% of \$250,000, (ii) divided by the per share grant date fair value that will be used for reporting the compensation expense associated with the Option under applicable accounting guidance.

b. The number of shares subject to the Restricted Stock Unit Award will be equal to (i) 35% of \$250,000, (ii) divided by the Fair Market Value of the Common Stock on the date of grant.

(2) Any person elected as or appointed to become a Non-Employee Director at a time other than at the Annual Meeting, upon the date of such election or appointment, will be granted:

a. an Option to purchase the number of shares determined by multiplying the number of shares as determined pursuant to 5(b)(iv)(1)(a) by a fraction, the numerator of which will be the number of days between the date of such election and the date which is the first anniversary of the date of the last preceding Annual Meeting, and the denominator of which will be 365, and

b. a Restricted Stock Unit Award for the number of shares determined by multiplying the number of shares as determined pursuant to 5(b)(iv)(1)(b) by a fraction, the numerator of which will be the number of days between the date of such election and the date which is the first anniversary of the date of the last preceding Annual Meeting, and the denominator of which will be 365.

(c) **Determination of Initial and Annual Grants.** The Board may, at any time, provide for Initial and Annual Grants covering a number of shares of Common Stock different than those numbers designated in Sections 5(a) and 5(b), respectively, and may provide that some or all of such grants may instead be in any of the forms of Stock Awards described in Section 7. If the Board does not make such a determination, all Initial and Annual Grants shall be for the number of shares of Common Stock designated in Section 5(a) and 5(b), respectively and in the form of Options described in Section 6.

(d) **Discretionary Grants.** In addition to non-discretionary grants pursuant to Sections 5(a) and 5(b), the Board, in its sole discretion, may grant Stock Awards to one or more Non-Employee Directors in such numbers and subject to such other provisions as it shall determine. The numbers and other provisions of such Stock Awards need not be identical.

6. **Provisions Relating to Options and Stock Appreciation Rights.**

Each Option or SAR shall be in such form and shall contain such terms and conditions as required by the Plan. Each Option or SAR shall contain such additional terms and conditions, not inconsistent with the Plan, as the Board shall deem appropriate. Each Option or SAR shall include (through incorporation of provisions hereof by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following provisions:

(a) **Term.** No Option or SAR shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Stock Award Agreement.

(b) **Exercise Price.** The exercise price (or strike price) of each Option or SAR shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Option or SAR is granted

(c) **Purchase Price for Options.** The purchase price of Common Stock acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by applicable law, by any combination of the following methods of payment:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

- (iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock; or
- (iv) by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued; *provided, further*, that shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations.

(d) **Exercise and Payment of a SAR.** To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right, and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) the strike price that will be determined by the Board at the time of grant of the Stock Appreciation Right. The appreciation distribution in respect to a Stock Appreciation Right may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(e) **Transferability.** An Option or SAR shall not be transferable except by will or by the laws of descent and distribution and to such further extent as permitted by the Rule as to Use of Form S-8 specified in the General Instructions of the Form S-8 Registration Statement under the Securities Act, and shall be exercisable during the lifetime of the Participant only by the Participant. Notwithstanding the foregoing, the Participant may, by delivering written notice to the Company, in a form satisfactory to the Company, designate a third party who, in the event of the death of the Participant, shall thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant’s estate shall be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise.

(f) **Option Vesting Generally.** Options shall vest as follows:

(i) **Initial Grant.** Thirty-three percent (33%) of the shares shall vest on the first anniversary of the date of such Initial Grant recipient’s election as a Non-Employee Director and the remaining sixty-seven percent (67%) of the shares shall vest in a series of twenty-four (24) successive equal monthly installments over the two (2)-year period following the first anniversary of the date of election, subject to Participant’s Continuous Service as of each such date.

(ii) **Annual Grant.**

(1) *Annual Grants awarded prior to January 14, 2013.* Fifty percent (50%) of the shares shall vest on the first anniversary of the date of grant and the remaining fifty percent (50%) of the shares shall vest in a series of twelve (12) successive equal monthly installments over the twelve (12)-month period following the first anniversary of the date of grant, subject to Participant’s Continuous Service as of each such date; *provided, however* that at the date of the second Annual Meeting following the date of grant, the unvested portion of the Annual Grant, if any, shall become fully vested and exercisable immediately prior to the date of such Annual Meeting.

(2) *Annual Grants awarded on or after January 14, 2013.* One hundred percent (100%) of the shares shall vest on the earlier of (i) the first anniversary of the date of grant and (ii) the date

of the first Annual Meeting following the date of grant, in each case subject to Participant's Continuous Service as of such date.

(iii) **Discretionary Grant.** At the time of grant of an Option pursuant to Section 5(d), the Board may impose such restrictions or conditions to the vesting of the Options as it, in its sole discretion, deems appropriate.

(g) **Termination of Continuous Service.** In the event that a Participant's Continuous Service terminates (other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Stock Award Agreement, which period shall not be less than 30 days), or (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Stock Award Agreement (as applicable), the Option or SAR (as applicable) shall terminate.

(h) **Extension of Termination Date.** In the event that the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR shall terminate on the earlier of (i) the expiration of a total period of three (3) months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement. In addition, unless otherwise provided in a Participant's Stock Award Agreement, if the sale of any Common Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service would violate the Company's insider trading policy, then the Option or SAR shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

(i) **Disability of Participant.** In the event that a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service or (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the time specified herein or in the Stock Award Agreement (as applicable), the Option or SAR (as applicable) shall terminate.

(j) **Death of Participant.** In the event that (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the three (3) month period after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date eighteen (18) months following the date of death, or (ii) the expiration of the term of such Option or SAR as set forth in the Stock Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the time specified herein, the Option or SAR (as applicable) shall terminate.

7. **Provisions Relating to Stock Awards other than Options and SARs.**



(a) **Restricted Stock Awards.** Each Restricted Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical; provided, however, that each Restricted Stock Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) **Vesting.** Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) **Termination of Participant's Continuous Service.** If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) **Transferability.** Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board shall determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) **Dividends.** A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) **Restricted Stock Unit Awards.** Each Restricted Stock Unit Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical; *provided, however*, that each Restricted Stock Unit Award Agreement shall conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) **Consideration.** At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) **Vesting.** At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) **Payment.** A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) **Additional Restrictions.** At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the

shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) **Dividend Equivalents.** Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) **Termination of Participant's Continuous Service.** Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) **Other Stock Awards.** Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 6 and the preceding provisions of this Section 7. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

#### 8. **Covenants of the Company.**

(a) **Availability of Shares.** During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock reasonably required to satisfy such Stock Awards.

(b) **Securities Law Compliance.** The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however*, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant shall not be eligible for the grant of a Stock Award or the subsequent issuance of Common Stock pursuant to the Stock Award if such grant or issuance would be in violation of any applicable securities law.

(c) **No Obligation to Notify or Minimize Taxes.** The Company shall have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

#### 9. **Miscellaneous.**

(a) **Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

(b) **Stockholder Rights.** No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until (i) such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Stock Award has been entered into the books and records of the Company.

(c) **No Service Rights.** Nothing in the Plan, any instrument executed thereunder, or Stock Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate as a Non-Employee Director or shall affect the right of the Company or an Affiliate to terminate the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(d) **Investment Assurances.** The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(e) **Withholding Obligations.** The Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise or acquisition of Common Stock under a Stock Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Participant by the Company) or by a combination of such means: (i) tendering a cash payment; (ii) authorizing the Company to withhold shares from the shares of Common Stock issued or otherwise issuable to the Participant as a result of the exercise or acquisition of Common Stock under the Stock Award; *provided, however,* that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) authorizing the Company to withhold cash from a Stock Award settled in cash; (iv) authorizing the Company to withhold payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Stock Award Agreement.

(f) **Electronic Delivery.** Any reference herein to a "written" agreement or document shall include any agreement or document delivered electronically or posted on the Company's intranet.

(g) **Deferrals.** To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Stock Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is providing services to the Company. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(h) **Compliance with Section 409A.** To the extent that the Board determines that any Stock Award granted hereunder is subject to Section 409A of the Code, the Stock Award Agreement evidencing such Stock Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Stock Award Agreements shall be interpreted in accordance with Section 409A of the Code. Notwithstanding anything to the contrary in this

Plan (and unless the Stock Award Agreement specifically provides otherwise), if the shares are publicly traded and a Participant holding a Stock Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount shall be made upon a “separation from service” before a date that is six (6) months following the date of such Participant’s “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant’s death.

10. **Adjustments upon Changes in Common Stock; Other Corporate Events.**

(a) **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and number of securities for which the nondiscretionary grants of Stock Awards are made pursuant to Section 5, and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

(b) **Dissolution or Liquidation.** In the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company’s right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company’s repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service, provided, however, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) **Corporate Transaction.** In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board shall take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation’s parent company);

(iii) accelerate the vesting of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award, over (B) any exercise price payable by such holder in connection with such exercise.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

11. **Amendment of the Plan and Stock Awards.**

(a) **Amendment of Plan.** Subject to the limitations, if any, of applicable law, the Board, at any time and from time to time, may amend the Plan. However, except as provided in Section 10(a) relating to Capitalization Adjustments, no amendment shall be effective unless approved by the stockholders of the Company to the extent stockholder approval is necessary to satisfy applicable law.

(b) **Stockholder Approval.** The Board, in its sole discretion, may submit any other amendment to the Plan for stockholder approval.

(c) **No Impairment of Rights.** Rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the affected Participant, and (ii) such Participant consents in writing.

(d) **Amendment of Stock Awards.** The Board, at any time and from time to time, may amend the terms of any one or more Stock Awards; *provided, however*, that the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the Participant, and (ii) the Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Stock Awards without the affected Participant's consent if necessary to bring the Stock Award into compliance with Section 409A of the Code.

12. **Termination or Suspension of the Plan**

(a) **Plan Term.** The Board may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) **No Impairment of Rights.** Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

13. **Effective Date of Plan.**

This Plan shall become effective on the IPO Date, but no Stock Award shall be exercised (or in the case of a Restricted Stock Award, Restricted Stock Unit Award, or Other Stock Award shall be granted) unless and until the Plan has been approved by the stockholders of the Company, which approval shall be within twelve months before or after the date the Plan is adopted by the Board.

14. **Choice of Law.**

The law of the state of Iowa shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

15. **Definitions.** As used in the Plan, the following definitions shall apply to the capitalized terms indicated below:

(a) **"Affiliate"** means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board shall have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) **"Annual Grant"** means an Option granted to a Non-Employee Director pursuant to Section 5(b).

(c) **"Annual Meeting"** means the first annual meeting of the stockholders of the Company held each fiscal year at which the Directors are selected.

(d) **"Board"** means the Board of Directors of the Company.

(e) **"Capitalization Adjustment"** means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date

without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards No. 123 (revised). Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a Capitalization Adjustment.

(f) **“Change in Control”** means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the **“Subject Person”**) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the **“Incumbent Board”**) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

In the event that a Change in Control affects any Stock Award that is deferred, then “Change in Control” shall conform to the definition of Change of Control under Section 409A of the Code, as amended, and the Treasury Department or Internal Revenue Service Regulations or Guidance issued thereunder.

(g) “**Code**” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(h) “**Committee**” means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(i) “**Common Stock**” means the common stock of the Company.

(j) “**Company**” means NewLink Genetics Corporation, a Delaware corporation.

(k) “**Consultant**” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(l) “**Continuous Service**” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, shall not terminate a Participant’s Continuous Service; *provided, however*, if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant’s Continuous Service shall be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board, in its sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of (i) any leave of absence approved by the Board, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(m) “**Corporate Transaction**” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) the consummation of a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) the consummation of a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(n) “**Director**” means a member of the Board.

(o) “**Disability**” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and shall be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(p) “**Effective Date**” means the effective date of this Plan document, as set forth in Section 13.

(q) “**Employee**” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an “Employee” for purposes of the Plan.

(r) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(s) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(t) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company’s then outstanding securities.

(u) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value shall be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(v) “**Initial Grant**” means an Option granted to a Non-Employee Director pursuant to Section 5(a).

(w) “**IPO Date**” means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(x) “**Non-Employee Director**” means a Director who is not an Employee.

(y) “**Nonstatutory Stock Option**” means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.



- (z) “**Officer**” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.
- (aa) “**Option**” means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to Section 6 of the Plan.
- (ab) “**Option Agreement**” means a written agreement between the Company and a Participant evidencing the terms and conditions of an individual Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.
- (ac) “**Other Stock Award**” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 7(c).
- (ad) “**Other Stock Award Agreement**” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement shall be subject to the terms and conditions of the Plan.
- (ae) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” A person or Entity shall be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.
- (af) “**Participant**” means a Non-Employee Director to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.
- (ag) “**Plan**” means this NewLink Genetics Corporation 2010 Non-Employee Directors’ Stock Award Plan.
- (ah) “**Restricted Stock Award**” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(a).
- (ai) “**Restricted Stock Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement shall be subject to the terms and conditions of the Plan.
- (aj) “**Restricted Stock Unit Award**” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(b).
- (ak) “**Restricted Stock Unit Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement shall be subject to the terms and conditions of the Plan.
- (al) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.
- (am) “**Securities Act**” means the Securities Act of 1933, as amended.
- (an) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 6.
- (ao) “**Stock Appreciation Right Agreement**” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.
- (ap) “**Stock Award**” means any right to receive Common Stock granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right or any Other Stock Award.
- (aq) “**Stock Award Agreement**” means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.
- (ar) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes

of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

**NewLink Genetics Corporation**  
**2010 Non-Employee Director Stock Award Plan, as Amended**  
**Restricted Stock Unit Award Agreement**

Pursuant to the Restricted Stock Unit Grant Notice (the “**Grant Notice**”) and this Restricted Stock Unit Award Agreement (the “**Agreement**”), NewLink Genetics Corporation (the “**Company**”) has awarded you (“**Participant**”) a Restricted Stock Unit Award (the “**Award**”) pursuant to Section 7(b) of the Company’s 2010 Non-Employee Director Stock Award Plan, as amended (the “**Plan**”) for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. **Grant of the Award.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “**Account**”) the number of Restricted Stock Units/shares of Common Stock subject to the Award. This Award was granted in consideration of your services to the Company.

2. **Vesting.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Restricted Stock Units/shares of Common Stock credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such underlying shares of Common Stock. In addition, if the Company is subject to a Change in Control before your Continuous Service terminates, then all of the unvested shares subject to this Award shall become fully vested immediately prior to the effective date of such Change in Control.

3. **Number of Shares.** The number of Restricted Stock Units/shares subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. **Securities Law Compliance.** You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. **Transfer Restrictions.** Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) **Death.** Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) **Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order or marital settlement agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. **Date of Issuance.**

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the withholding obligations set forth in this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above). The issuance date determined by this paragraph is referred to as the “**Original Issuance Date**”.

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an “open window period” applicable to you, as determined by the Company in accordance with the Company’s then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, *and*

(ii) either (1) Withholding Taxes do not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Taxes by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to pay your Withholding Taxes in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company’s Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a “substantial risk of forfeiture” within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. **Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment.

8. **Restrictive Legends.** The shares of Common Stock issued under your Award shall be endorsed with appropriate legends as determined by the Company.

9. **Execution of Documents.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. **Award not a Service Contract.**

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) The Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a “**reorganization**”). Such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. This Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company’s right to conduct a reorganization.

11. **Withholding Obligations.**

(a) On each vesting date, and on or before the time you receive a distribution of the shares underlying your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the “**Withholding Taxes**”). Additionally, the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a “same day sale” commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a “**FINRA Dealer**”) whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued to pursuant to Section 6) equal to the amount of such Withholding Taxes; *provided, however*, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company’s required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided, further*, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Company’s Compensation Committee.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(c) In the event the Company’s obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company’s withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. **Tax Consequences.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. **Notices.** Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (i) the date of personal delivery, including delivery by express courier, or delivery via electronic means, or (ii) the date that is five (5) days after deposit in the United States Post Office (whether or not actually received by the addressee), by registered or certified mail with postage and fees prepaid, addressed at the following addresses, or at such other address(es) as a party may designate by ten (10) days' advance written notice to each of the other parties hereto:

**Company:** NewLink Genetics Corporation  
 Attn: Stock Administrator  
 2503 South Loop Drive  
 Ames, Iowa 50010

**Participant:** Your address as on file with the Company  
 at the time notice is given

15. **Headings.** The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. **Miscellaneous.**

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. **Governing Plan Document.** Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations,

amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for “good reason,” or for a “constructive termination” or any similar term under any plan of or agreement with the Company.

18. **Effect on Other Employee Benefit Plans.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. **Choice of Law.** The interpretation, performance and enforcement of this Agreement shall be governed by the law of the State of Iowa without regard to that state’s conflicts of laws rules.

20. **Severability.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. **Other Documents.** You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company’s *Insider Trading and Trading Window Policy*.

22. **Amendment.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

23. **Compliance with Section 409A of the Code.** This Award is intended to comply with the “short-term deferral” rule set forth in Treasury Regulation Section 1.409A-1(b)(4). Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise deferred compensation subject to Section 409A, and if you are a “Specified Employee” (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your “separation from service” (within the meaning of Treasury Regulation Section 1.409A-1(h) and without regard to any alternative definition thereunder), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a “separate payment” for purposes of Treasury Regulation Section 1.409A-2(b)(2).

\* \* \* \* \*

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.



May 22, 2015

W. Jay Ramsey, M.D., Ph.D.  
1909 NW Pleasant Street  
Ankeny, IA 50023

**Re: Your Retirement**

Dear Jay:

You have informed us that you wish to retire from NewLink Genetics Corporation (the “**Company**”) effective May 22, 2015. This letter agreement (the “**Agreement**”) sets forth the benefits we have agreed to provide you in recognition of your exemplary service and many contributions to the Company’s success.

1. **Retirement Date and Final Salary Payment.** You hereby resign from your position as Clinical and Regulatory Compliance Officer of the Company, and from any other office or position you may hold with the Company or any affiliated entity, effective as of May 22, 2015 (the “**Retirement Date**”). On the next payroll date following your Retirement Date, the Company will pay you all accrued salary earned, and all accrued unused vacation, through the Retirement Date, subject to standard payroll deductions and withholdings. You are entitled to this payment regardless of whether or not you sign this Agreement.

2. **Retirement Benefits.** In consideration for the release of claims you are providing herein, and for all other promises you are making and obligations you are undertaking in this Agreement, if you sign this Agreement, allow it to become effective, and comply with your obligations under it, the Company shall provide you with the following retirement benefits (the “**Retirement Benefits**”):

(a) **Special Bonus Payment.** On the first regular payroll date after 10 business days after the Retirement Date or the Effective Date of this Agreement, the Company will pay you a special bonus equal to six (6) months of your base salary in effect as of the Retirement Date (the “**Special Bonus Payment**”), totaling \$172,900, subject to standard withholdings and deductions.

(b) **Healthcare Continuation Coverage and Premium Payments.**

(i) **COBRA.** To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company’s current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense after your Retirement Date. Later, you may be able to convert to an individual policy through the provider of the Company’s health insurance, if you wish to do so.

(ii) **COBRA Premiums.** If you timely elect continued coverage under COBRA, the Company will pay your COBRA premiums for continuation of your basic medical, dental and vision coverage (including coverage for eligible dependents, if applicable) (“**COBRA Premiums**”) through the period (the “**COBRA Premium Period**”) starting on your Retirement Date and ending on the earliest to occur of: (i) November 30, 2015; (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event you become covered under another employer’s group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you shall immediately provide written notification of such event to the Company’s Human Resources manager.

(iii) **Alternative Cash Payments in Lieu of COBRA Premiums.** Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), the Company instead shall pay you, on the first day of each calendar month following

such determination, a fully taxable cash payment equal to the applicable COBRA premiums for that month (including premiums for you and your eligible dependents who have elected and remain enrolled in such COBRA coverage), subject to applicable tax withholdings (such amount, the “**Alternative Cash Payment**”), for the remainder of the COBRA Premium Period. You may, but are not obligated to, use such Alternative Cash Payments toward the cost of COBRA premiums.

(c) **Equity Vesting and Extended Exercise.** You have been granted options to purchase shares of the Company’s common stock (the “**Options**”) and certain restricted stock units (the “**RSUs**”) pursuant to the Company’s 2000 and/or 2009 Equity Incentive Plans (the “**Plans**”). Under the terms of the applicable governing agreements and Plan documents, vesting of any unvested Options or RSUs would cease on your Retirement Date. However, as an additional benefit under this Agreement, the Company will: (a) accelerate the vesting of all of your outstanding and unvested equity awards that were granted on or prior to December 31, 2014 (the “**Accelerated Grants**”) such that one-hundred percent (100%) of the shares subject to such Options underlying the Accelerated Grants shall be deemed vested and exercisable as of the Retirement Date (the “**Accelerated Vesting**”); and (b) extend your exercise period under the governing agreements and Plan documents so that you shall have until December 31, 2015 to exercise any or all of your vested Options (including any options accelerated hereunder) (the “**Extended Exercise Period**”). All equity awards that were granted to you on or subsequent to January 1, 2015 will vest according to their terms through the Retirement Date. Except as expressly provided in this Section, the Options and the RSUs held by you will continue to be governed by the terms of the governing agreements and Plan documents. You acknowledge and agree that for any portion of the Options previously classified as incentive stock options, extending the exercise period may change their tax treatment; and you should seek advice from your own tax advisors on this extension.

3. **Other Compensation or Benefits.** You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive after your Retirement Date any additional compensation, severance or benefits, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (e.g., 401(k) account). By way of example, you acknowledge that you have not earned and are not owed any bonus, vacation, incentive compensation, commissions or equity (other than as provided or referenced herein).

4. **Expense Reimbursements.** You agree that, within thirty (30) days of your Retirement Date, you will submit to the Company your final documented expense reimbursement statement reflecting all business expenses you incurred through the Retirement Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

5. **Return of Company Property.** No later than the close of business on your Retirement Date, you shall return to the Company all Company documents (and all copies thereof) and other Company property or information in your possession or control (collectively, “**Company Property**”), including, but not limited to: Company hardcopy and softcopy files, databases, notes, emails, correspondence, financial and operational information, current or potential customer lists and contact information, product and services information, research and development information, drawings, records, plans, forecasts, reports, payroll information, spreadsheets, studies, analyses, compilations of data, proposals, agreements, sales and marketing information, personnel information, specifications, code, software, electronically or computer-recorded information, tangible property and equipment (including, but not limited to, computing and communications devices, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company and all reproductions or embodiments thereof in whole or in part and in any medium. You shall make a diligent search to locate any such Company Property by the close of business on your Retirement Date. In addition, if you have used any personally owned computing or communication device, server, or e-mail system to receive, store, review, prepare or transmit any confidential or proprietary data, materials or information of the Company, then within five (5) business days after your Retirement Date, you shall permanently delete and expunge such confidential or proprietary information from those systems without

retaining any reproductions (in whole or in part); and you agree to make any such device or system available for inspection and analysis by the Company, upon its request, in order to permit the Company to determine whether you are in compliance with the provisions of this Section. **Your timely compliance with the provisions of this Section is a precondition to your receipt of the Retirement Benefits and other benefits provided hereunder.**

6. **Proprietary Information, Non-Solicitation and Non-Competition Obligations.** You acknowledge your continuing obligations under your Employee Proprietary Information, Inventions, Non-Competition, and Non-Solicitation Agreements executed on March 7, 2013 (attached hereto as **Exhibit A**), effective as of the beginning of your employment with the Company and continuing (as provided therein) following the Retirement Date, including but not limited to your obligations not to use or disclose any confidential or proprietary information of the Company and comply with your post-employment non-competition and non-solicitation restrictions.

7. **Confidentiality.** The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; provided, however, that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law.

8. **Public Statements.** Both the Company and you shall respond to third party inquiries, and the Company may issue a press release, effectively stating that you have retired from your position as Clinical and Regulatory Compliance Officer, and from your employment with the Company, effective as of the Retirement Date.

9. **Cooperation.**

(a) **Transition Briefings.** You agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, transitioning any work relationships and providing detailed oral and written briefings (as requested) with respect to any past or present work activities and institutional knowledge, to such other persons as may be designated by the Company. By way of example and not limitation, in the event that the Company's Executives requests transition briefing information from you regarding any Company matters that were within your areas of responsibility, in which you were involved, or about which you are knowledgeable, you will make yourself available to respond to such inquiries with reasonable promptness, either telephonically or by email (as requested), unless the Company requests that you come to the Company for such discussion or to review certain documents or materials related to the inquiry.

(b) **No Voluntary Adverse Assistance.** You agree that you will not voluntarily provide assistance, information or advice, directly or indirectly (including through agents or attorneys), to any third party (including both persons and entities) in connection with any claim or cause of action of any kind brought against, or being prepared against, the Company by any third party, nor shall you induce or encourage any person or entity to bring such claims; provided, however, that you may respond accurately and fully to any questions, inquiry or request for information as required by legal process (e.g., a valid subpoena or other similar compulsion of law) or in response to a specific inquiry in a government investigation.

(c) **Other Voluntary Cooperation.** You agree to cooperate fully with the Company in connection with its actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters arising from events, acts, or failures to act that occurred during the period of your employment by the Company. Such cooperation includes, without limitation, making yourself available to the Company upon reasonable notice, without subpoena, to provide complete, truthful and accurate information in witness interviews, depositions, and trial testimony. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding forgone wages, salary, or other compensation), and will make reasonable efforts to accommodate your scheduling needs. In addition, you agree to execute all documents (if any) necessary to carry out the terms of this Agreement.

10. **No Admissions.** Nothing contained in this Agreement shall be construed as an admission by you or the Company of any liability, obligation, wrongdoing or violation of law.

11. **General Release of Claims.**

(a) **General Release.** In exchange for the Severance Benefits and any other commitments by the Company herein, you hereby generally and completely release the Company and its parent or subsidiary entities, successors, predecessors and affiliates, and its and their directors, officers, employees, consultants, shareholders, agents, attorneys, insurers, affiliates and assigns (collectively, the “**Released Parties**”) of and from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or on the date you sign this Agreement (collectively, the “**Released Claims**”). You hereby covenant not to file any lawsuits, administrative proceedings, charges or other claims with regard to the Released Claims, other than the Excluded Claims described below.

(b) **Scope of Release.** The Released Claims include, but are not limited to: (i) all claims arising from or in any way related to your employment with the Company, or the termination of that employment; (ii) all claims related to your compensation or benefits from the Company (except as expressly provided herein), including but not limited to salary, bonuses, commissions, vacation pay, paid time off, expense reimbursement, severance pay, fringe benefits, profit sharing, stock, stock options, or any other ownership or equity interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing, including but not limited to any claims arising under or based on your employment offer letter or subsequent Employment Agreement; (iv) all tort claims, including but not limited to claims for battery, negligence, fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including but not limited to claims for discrimination, harassment, retaliation, attorneys’ fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Family and Medical Leave Act (as amended) (“**FMLA**”), the federal Age Discrimination in Employment Act of 1967 (as amended) (the “**ADEA**”), the Equal Pay Act of 1963, the Fair Labor Standards Act, the Employee Retirement Income Security Act of 1974 (as amended) as related to severance benefits, the Iowa Civil Rights Act of 1965 and the Iowa Wage Payment Collection Law.

(c) **Excluded Claims.** Notwithstanding the foregoing, the following are not included in the Released Claims (the “**Excluded Claims**”): (i) rights to unemployment insurance benefits; (ii) rights to any workers’ compensation disability benefits, claims and payments, if applicable; (iii) any rights or claims for indemnification you may have pursuant to any written indemnification agreement with the Company to which you are a party, or under Company bylaws or articles, or under applicable law; (iv) any rights which are not waivable as a matter of law; and (v) any claims for breach of this Agreement. In addition, nothing in this Agreement prevents you from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the Iowa Civil Rights Commission, or any other government agency, provided that you agree that you hereby waive your right to any monetary benefits in connection with any such claim, charge or proceeding. You represent and warrant that, other than the Excluded Claims, you are not aware of any claims you have or may have against any of the Released Parties that are not included in the Released Claims.

(d) **ADEA Waiver.** You acknowledge that, by giving the general release above, you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA, and that the consideration given for the waiver and releases you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (a) your waiver and release does not apply to any rights or claims arising after the date you sign this Agreement; (b) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (c) you have twenty-one (21) days to consider this Agreement (although you may choose voluntarily to sign it sooner); (d) you have seven (7) days following the date you sign this Agreement to revoke this Agreement (in a written revocation sent to the Company’s Chief Executive

Officer); and (e) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement, provided that you do not revoke it (the “**Effective Date**”).

12. **Representations.** You hereby represent that you have been paid all compensation owed and for all hours worked, have received all leave and leave benefits and protections for which you are eligible, pursuant to the Family and Medical Leave Act or otherwise, and have not suffered any on-the-job injury for which you have not already filed a claim.

13. **Section 409A.**

(a) **Compliance and Interpretation.** Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Internal Revenue Code of 1986, as amended (the “**Code**”) and the regulations and other guidance thereunder and any state law of similar effect (collectively “**Section 409A**”). It is intended that all of the benefits and payments under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be interpreted accordingly. To the extent not so exempt, this Agreement (and any definitions hereunder) will be interpreted in a manner that complies with the Section 409A requirements. For purposes of Section 409A, your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

(b) **Required Six Month Delay For Deferred Compensation Payments.** Notwithstanding any provision to the contrary in this Agreement, because you are deemed by the Company to be a “specified employee” for purposes of Code Section 409A(a)(2)(B)(i), and the Deferred Salary Payment is deemed to be “deferred compensation,” subject to the Section 409A requirements, then in order to avoid adverse tax consequences to you under Section 409A, the Deferred Salary Payment will not be made to you until the first regularly scheduled payroll date that is six (6) months after the Retirement Date (the “**Deferred Initial Payment Date**”), on which date the Company will pay to you (or your beneficiaries) a lump sum amount equal to the sum of the payments otherwise scheduled to be made prior to the Deferred Initial Payment Date. No interest will be paid to you on any amounts for which payment is delayed pursuant to the foregoing provision.

14. **General.** This Agreement, including Exhibit A, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other agreements, promises, warranties or representations concerning its subject matter between you and the Company, the Employment Agreement between you and the Company dated November 22, 2010 and the First Amendment to Employment Agreement between you and the Company dated August 13, 2013). This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable to the fullest extent permitted by law, consistent with the intent of the parties. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Iowa without respect to conflicts of law principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement may be executed in counterparts which shall be deemed to be part of one original, and facsimile and electronic (e.g., PDF) copies of signatures shall be equivalent to original signatures.

To accept the terms set forth above, please sign and date this Agreement and return the fully-executed Agreement to the Company.

We wish you the best in your future endeavors.

Sincerely,

**NewLink Genetics Corporation**

By: /s/Charles J. Link, Jr. MD  
Charles J. Link, Jr. MD  
Chairman, Chief Executive Officer, and Chief Scientific Officer

**Understood and Agreed:**

/s/ W. Jay Ramsey, M.D., Ph.D.  
W. Jay Ramsey, M.D., Ph.D.

Date May 22, 2015

**Exhibit A**

**EMPLOYEE PROPRIETARY INFORMATION, INVENTIONS, NON-COMPETITION, AND NON-SOLICITATION  
AGREEMENT**

## CERTIFICATION

I, Charles J. Link, Jr., certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: August 6, 2015

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

## CERTIFICATION

I, John B. Henneman III, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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: August 6, 2015

By: /s/ John B Henneman III

John B. Henneman III

Chief Financial Officer and Secretary

(Principal Financial Officer)



## 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 and Secretary of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2015, 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: August 6, 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 and Secretary

(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-Q 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-Q), irrespective of any general incorporation language contained in such filing.