

**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, 2014.

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number

001-35342

**NEWLINK GENETICS CORPORATION**

(Exact name of Registrant as specified in Its Charter)

**Delaware**

**42-1491350**

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

**2503 South Loop Drive**

**Ames, Iowa 50010**

**(515) 296-5555**

(Address, including zip code, and telephone number, including area code, of principal executive offices)

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 31, 2014, there were 27,909,031 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)**

	June 30, 2014	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 76,861	\$ 61,291
Certificates of deposit	249	249
Prepaid expenses	446	773
State research and development credit receivable	497	329
Other receivables	161	1,328
Total current assets	78,214	63,970
Leasehold improvements and equipment:		
Leasehold improvements	5,577	5,588
Computer equipment	1,261	1,133
Lab equipment	3,994	3,724
Total leasehold improvements and equipment	10,832	10,445
Less accumulated depreciation and amortization	(4,376)	(3,858)
Leasehold improvements and equipment, net	6,456	6,587
<b>Total assets</b>	<b>\$ 84,670</b>	<b>\$ 70,557</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)**

	June 30, 2014	December 31, 2013
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 687	\$ 612
Accrued expenses	2,891	2,861
Income taxes payable	5	130
Current portion of deferred rent	84	84
Current portion of long term debt and obligations under capital leases	190	189
Total current liabilities	3,857	3,876
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	937	1,033
Deferred rent, excluding current portion	1,279	1,321
Total long-term liabilities	8,216	8,354
Total liabilities	12,073	12,230
Commitments and contingencies		
Stockholders' Equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares — 5,000,000 at June 30, 2014 and December 31, 2013; issued and outstanding shares — 0 at June 30, 2014 and December 31, 2013	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 at June 30, 2014 and December 31, 2013; issued shares — 27,912,198 and outstanding shares — 27,903,705 at June 30, 2014, and issued and outstanding shares — 26,573,023 at December 31, 2013	279	266
Additional paid-in capital	226,876	194,038
Treasury stock, at cost: 8,493 shares at June 30, 2014	(182)	—
Retained deficit	(154,376)	(135,977)
Total stockholders' equity	72,597	58,327
Total liabilities and stockholders' equity	\$ 84,670	\$ 70,557

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)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Grant revenue	\$ 212	\$ 232	\$ 546	\$ 534
Operating expenses:				
Research and development	6,475	5,037	12,863	11,380
General and administrative	2,863	2,264	6,114	4,265
Total operating expenses	<u>9,338</u>	<u>7,301</u>	<u>18,977</u>	<u>15,645</u>
Loss from operations	(9,126)	(7,069)	(18,431)	(15,111)
Other income and expense:				
Miscellaneous (expense) income	(50)	—	—	114
Interest income	21	2	45	4
Interest expense	(9)	(10)	(13)	(18)
Other income (expense), net	<u>(38)</u>	<u>(8)</u>	<u>32</u>	<u>100</u>
Net loss before taxes	(9,164)	(7,077)	(18,399)	(15,011)
Income tax expense	—	—	—	—
Net loss	<u>(9,164)</u>	<u>(7,077)</u>	<u>(18,399)</u>	<u>(15,011)</u>
Net loss per common share, basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.28)</u>	<u>\$ (0.66)</u>	<u>\$ (0.61)</u>
Weighted-average common shares outstanding, basic and diluted	<u>27,876,652</u>	<u>25,620,566</u>	<u>27,742,029</u>	<u>24,745,380</u>

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	Retained Deficit	Total Stockholders' Equity
Balance at December 31, 2013	26,573,023	\$ 266	\$ 194,038	\$ —	\$ (135,977)	\$ 58,327
Share-based compensation	—	—	3,604	—	—	3,604
Exercise of stock options	309,148	3	1,456	—	—	1,459
Sale of shares under stock purchase plan	12,810	—	233	—	—	233
Issuance of common stock under the ATM Offering (net of offering costs of \$692, January and February 2014)	1,017,217	10	27,545	—	—	27,555
Shares withheld for statutory tax withholding (January 2, 2014)	(8,493)	—	—	(182)	—	(182)
Net loss	—	—	—	—	(18,399)	(18,399)
Balance at June 30, 2014	<u>27,903,705</u>	<u>\$ 279</u>	<u>\$ 226,876</u>	<u>\$ (182)</u>	<u>\$ (154,376)</u>	<u>\$ 72,597</u>

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2014	2013
<b>Cash Flows From Operating Activities</b>		
Net loss	\$ (18,399)	\$ (15,011)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Share-based compensation	3,604	2,027
Depreciation and amortization	517	425
Changes in operating assets and liabilities:		
Prepaid expenses	327	372
State research and development credit receivable	(168)	107
Other receivables	1,167	(617)
Accounts payable	98	104
Income taxes payable	(125)	—
Accrued expenses and deferred rent	(124)	1,116
Net cash used in operating activities	<u>(13,103)</u>	<u>(11,477)</u>
<b>Cash Flows From Investing Activities</b>		
Maturity of certificates of deposit	—	1,245
Purchase of equipment	(297)	(274)
Net cash (used in) provided by investing activities	<u>(297)</u>	<u>971</u>
<b>Cash Flows From Financing Activities</b>		
Issuance of common stock, net of offering costs	29,247	49,416
Repurchase of common stock	(182)	—
Principal payments on notes payable	(77)	(74)
Payments under capital lease obligations	(18)	(47)
Net cash provided by financing activities	<u>28,970</u>	<u>49,295</u>
Net increase in cash and cash equivalents	15,570	38,789
Cash and cash equivalents at beginning of period	61,291	20,250
Cash and cash equivalents at end of period	<u>\$ 76,861</u>	<u>\$ 59,039</u>
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$ 13	\$ 18
Noncash financing and investing activities:		
Purchased leasehold improvements and equipment in accounts payable	89	71

See accompanying notes to condensed consolidated financial statements.

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

**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 of 2000, which primarily consist of research and development.

In 2005, NewLink created a wholly-owned subsidiary, BioProtection Systems Corporation (BPS). NewLink contributed certain licensing agreements and other intangible assets for BPS to create vaccines against potential biological terror threats. Subsequent to its creation, certain interests in BPS were sold to minority stockholders. 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). In 2014, NewLink created another wholly-owned subsidiary, NewLink Global (NG). NewLink plans to conduct all or a portion of its operations outside of the United States through NI and NG.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from sales of its drugs. The Company incurred a net loss of 9.2 million and 18.4 million for the three and six months ending June 30, 2014. The Company has managed its liquidity needs to date through a series of capital market transactions. On February 4, 2013, the Company completed an offering of its common stock. The Company sold 4,600,000 shares of common stock at a price of \$11.40 per share raising a total of \$49.0 million in net proceeds.

NewLink entered into a sales agreement with Cantor Fitzgerald & Co., dated as of September 5, 2013, under which NewLink may sell up to \$60.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the ATM Offering). Any such sales would be effected pursuant to its registration statement on Form S-3 (333-185721), declared effective by the SEC on January 4, 2013. As of June 30, 2014, the Company had sold 1,833,838 shares of common stock under the ATM Offering, raising a total of \$45.0 million in net proceeds. During the years ended December 31, 2013 and 2012, the Company received equity financing of \$67.2 million and \$1.3 million, respectively, through common stock offerings. Subsequent to March 31, 2014 and through the date of this filing, the Company sold no additional shares of common stock under the ATM Offering.

The accompanying financial statements as of June 30, 2014 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 initial public offering in 2011, completed a follow-on offering of its common stock raising net proceeds of \$49.0 million, and raised an additional \$45.0 million in net proceeds from the ATM Offering prior to June 30, 2014. The Company's cash and cash equivalents after these offerings are expected to be adequate to satisfy the Company's liquidity requirements well into 2015, 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.

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

## **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 (SEC), without audit, and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim 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, 2013, 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 2013. 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 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***

The fair values of cash and cash equivalents, certificates of deposit, receivables, and accounts payable, which are recorded at cost, approximate fair value based on the short-term nature of these financial instruments. The fair value and carrying value of notes payable and capital lease obligations was \$1.1 million and \$1.2 million as of June 30, 2014 and December 31, 2013, respectively, and was determined using Level 3 inputs. The Company is unable to estimate the fair value of the royalty obligation because the timing and receipt of payments 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 cash equivalents, such as money market funds, or 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, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

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

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

4. Long-Term Debt and Conversion to Royalty Obligation

*March 2010 City of Ames Forgivable Loan*

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

The project calls for the Company to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or maintain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2015, the Company has failed to create or retain at least 150 full-time jobs in Ames, Iowa, the Company will be required to repay approximately \$3,100 per job not created or retained following such date. As of December 31, 2013, \$300,000 of the total \$400,000 forgivable loan was advanced to the Company. The final \$100,000 available under the agreement was advanced to the Company on July 25, 2014. 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. Common Stock Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan (the "2000 Plan"), and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the "2009 Plan"). Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, 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. Shares are added to the reserve of shares available for issuance pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year. As of June 30, 2014, there were 6,799,854 shares of common stock authorized for the 2009 plan and 1,075,709 shares remained available for issuance.

On January 1, 2013, an additional 838,375 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2014 an additional 1,066,340 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan (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, 2014, 207,327 shares remained available for issuance under the plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan (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, 2014, 283,998 shares remained available for issuance under the plan.

***Share-based Compensation***

Share-based compensation expense for the three and six months ended June 30, 2014 and the three and six months ended June 30, 2013 was \$1.5 million, \$3.6 million, \$1.1 million, and \$2.0 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of \$0 for all periods.

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

As of June 30, 2014, the total compensation cost related to nonvested option awards not yet recognized was \$12.9 million and the weighted average period over which it is expected to be recognized is 2.9 years.

The following table summarizes the stock option activity for the six months ended June 30, 2014:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	4,486,564	\$ 5.89	
Options granted	604,805	23.24	
Options exercised	(269,148)	5.42	
Options forfeited	(17,371)	14.82	
Options expired	—	—	
Outstanding at end of period	4,804,850	\$ 8.07	6.7
Options exercisable at end of period	3,425,050	\$ 4.90	5.9

The following table summarizes options that were granted during the six months ended June 30, 2014, and the range of assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

Risk-free interest rate	1.86%-2.24%
Expected dividend yield	—%
Expected volatility	57.4%-62.4%
Expected term (in years)	6.0-7.0
Weighted average grant-date fair value per share	\$13.62

The intrinsic value of options exercised during the six months ended June 30, 2014 was \$6.9 million. The fair value of awards vested during the six months ended June 30, 2014 was \$3.8 million.

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for so long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a stockholder with respect to such stock, including the right to vote and to receive dividends thereon, except as otherwise provided in the award agreement relating to such award. Restricted stock awards are equity classified within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of Company's Common Stock on the The NASDAQ Stock Market on the date of grant.

During the six months ended June 30, 2014 and 2013, respectively, there were 133,420 and 0 shares of restricted stock granted. These restricted stock grants had a weighted average fair value (per share) at date of grant of \$21.71. At June 30, 2014, and December 31, 2013, there were 93,420 and 0 shares of unvested restricted stock outstanding, respectively. Compensation expense is determined for the issuance of restricted stock by amortizing over the requisite service period, or the vesting period, the aggregate fair value of the restricted stock awarded based on the closing price of the Company's common stock on the date of grant.

A summary of the Company's unvested restricted stock at June 30, 2014 and changes during the six months ended June 30, 2014 is as follows:

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

	Restricted Stock	Weighted Average Grant Date Fair Value
Unvested at December 31, 2013	—	\$ —
Granted	133,420	21.71
Vested	(40,000)	21.38
Forfeited/cancelled	—	—
Unvested restricted stock at June 30, 2014	<u>93,420</u>	<u>\$ 21.85</u>

As of June 30, 2014, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately \$1.8 million and is expected to be recognized over a weighted-average period of 3.1 years.

## 6. Income Taxes

The company incurred no income tax expense for the six months ended June 30, 2014 and 2013. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

The valuation allowance for deferred tax assets as of June 30, 2014 and December 31, 2013 was \$27.5 million and \$25.2 million, respectively. The net change in the total valuation allowance for the six months ended June 30, 2014 and 2013 was an increase of \$2.4 million and \$4.2 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, 2014 and December 31, 2013, due to the uncertainty of future recoverability.

Based on analysis from inception through December 31, 2011, we believe that 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 limit 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, 2011 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 our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company's stock or certain changes in the ownership of any of the Company's 5% stockholders.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2011 and/or changes in our ownership that resulted from our follow-on offering or our ATM Offering have caused or will cause another ownership change to occur. Any such change could result in significant limitations on some or all of our net operating loss carryforwards and other tax attributes.

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

## 7. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per

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

share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

	Six Months Ended June 30,	
	2014	2013
<b>Historical net loss per share</b>		
<b>Numerator</b>		
Net loss attributable to common stockholders	\$ (18,399)	\$ (15,011)
<b>Denominator</b>		
Weighted-average common shares outstanding (basic and diluted)	\$ 27,742,029	\$ 24,745,380
Basic and diluted net loss per share	\$ (0.66)	\$ (0.61)

As of June 30, 2014 and 2013 respectively, 4.9 million and 4.5 million common equivalent shares of potentially dilutive securities were not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive.

## 8. Commitments and Contingencies

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

## 9. Subsequent Events

The Company entered into a letter contract dated August 4, 2014, with the United States Defense Threat Reduction Agency. The letter contract is for \$1.0 million with additional funding subject to final negotiation and will fund Investigational New Drug (IND)-enabling pre-clinical toxicology studies and includes the manufacture of clinical materials.

## 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 immunotherapy; the timing of release of data from ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our 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, 2013. 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 immunotherapy product candidates intended to treat a wide range of oncology indications. Our product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. We have two proprietary cancer immunotherapy technology platforms that independently stimulate immune activation and disrupt tumor-mediated immunosuppression; HyperAcute vaccines which induce immune activation and IDO (Indoleamine 2,3-dioxygenase) pathway inhibitors which block immunosuppression.

Our lead HyperAcute product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. A second Phase 3 Trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients. We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival. We have received Fast Track and Orphan Drug designations from the FDA for algenpantucel-L for the adjuvant treatment of patients with surgically-resected pancreatic cancer and Orphan Medicinal Product designation for algenpantucel-L from the European Commission. The primary endpoint for our IMPRESS trial with algenpantucel-L for patients with surgically-resected pancreatic cancer is overall survival and, as determined by the SPA, the first interim analysis was conducted when 222 deaths were reported for the study, which occurred during the quarter ending March 31, 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 their review, the DSMC recommended that the study should proceed as planned, without modification. A second interim analysis is planned upon reaching 333 patient events and, if needed, a final analysis is planned at 444 patient events. Our additional Hyper Acute product candidates in clinical development include tergenpumatucl-L (HyperAcute Lung), dorgenmeltucl-L (HyperAcute Melanoma), HyperAcute Prostate and Hyper Acute Renal. To date, our HyperAcute product candidates have been dosed in more than 500 cancer patients, either as a monotherapy or in combination with other treatments and have demonstrated a favorable safety profile.

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

In addition to our HyperAcute platform, we have an active drug discovery and clinical development program focused on the IDO (indoleamine-(2,3)-dioxygenase) pathway. Our IDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. We currently have two distinct IDO pathway inhibitor product candidates in clinical development, indoximod and NLG919, with different and potentially complementary mechanisms of action. Additionally, we are conducting ongoing drug discovery work to explore new chemical entities, which inhibit IDO as well as a related target, TDO (tryptophan-2,3 dioxynase), as potential new anticancer agents. Our most advanced IDO pathway inhibitor, indoximod, is in multiple Phase 1 and 2 clinical trials for the treatment of patients with breast, prostate, pancreas, and brain cancers. Additionally, NLG919 is currently in Phase 1 clinical development for patients with recurrent advanced solid tumors. We have generated encouraging preclinical data that demonstrate the potential of combining multiple immunotherapies including multiple checkpoint inhibitors that target the IDO pathway for enhanced anti-tumor activity.

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

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

BioProtection Systems Corporation, or BPS, was founded by us as a subsidiary in 2005 to research, develop and commercialize vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism. BPS is based on three core technologies, each of which can be leveraged into the infectious disease or biodefense fields. The first is our HyperAcute immunotherapy technology, which is currently focused on enhancing vaccines for influenza. The second technology is based on a yellow fever virus. The third technology is a replication competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses.

We incurred net losses of 9.2 million, 18.4 million, 7.1 million, and 15.0 million, for the three and six months ended June 30, 2014 and the three and six months ended June 30, 2013, respectively. 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 begin to build 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.

**Financial Overview****Revenues**

During the three and six month periods ending June 30, 2014, and June 30, 2013, we did not generate any revenue from product sales. We generated grant revenue of \$212,000, \$546,000, \$232,000 and \$534,000, in grant revenue for the three and six months ended June 30, 2014, and the three and six months ended June 30, 2013, respectively, which is primarily attributable to research and development being performed by our subsidiary, BPS, under contracts and grants with the Department of Defense, or DOD, and the National Institutes of Health, or NIH.

In the future, we may generate revenue from a variety of sources, including product sales (if we develop products that are approved for sale), license fees, and milestone, research and development and royalty payments in connection with strategic collaborations or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

**Research and Development Expenses**

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

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

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidates, and to further advance our earlier-stage research and development projects. The following tables summarize our research and development expenses for the periods indicated:

**Research and Development Expenses by Product**  
(In thousands)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
HyperAcute immunotherapy technology	\$ 4,898	\$ 3,877	\$ 9,579	\$ 7,711
IDO pathway inhibitor technology	1,205	835	2,402	2,920
Other research and development	372	325	882	749
Total research and development expenses	<u>\$ 6,475</u>	<u>\$ 5,037</u>	<u>\$ 12,863</u>	<u>\$ 11,380</u>

**Research and Development Expenses by Category**  
**(In thousands)**  
**(unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Compensation	\$ 2,933	\$ 2,198	\$ 6,180	\$ 4,537
Equipment, supplies and occupancy	1,303	1,259	2,750	2,588
Outside clinical and other	2,239	1,580	3,933	4,255
Total research and development expenses	<u>\$ 6,475</u>	<u>\$ 5,037</u>	<u>\$ 12,863</u>	<u>\$ 11,380</u>

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

**General and Administrative Expenses**

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

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

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

**Interest Income and Interest Expense**

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

Interest expense consists primarily of interest and amortization of deferred financing costs associated with our notes payable and obligations under capital leases.

**Tax Loss Carryforwards**

The valuation allowance for deferred tax assets as of June 30, 2014 and December 31, 2013 was \$27.5 million and \$25.2 million, respectively. The net change in the total valuation allowance for the three months ended June 30, 2014 and 2013 was

an increase of \$2.4 million and \$4.2 million, respectively. In assessing the realizability of deferred tax assets, we consider 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. We consider 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, 2014 and December 31, 2013, due to the uncertainty of future recoverability.

As of June 30, 2014 and December 31, 2013, we had federal net operating loss carryforwards of \$97.9 million and \$88.4 million and federal research credit carryforwards of \$4.3 million and \$4.3 million, respectively, that expire at various dates from 2019 through 2034. 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, 2011, we believe that we 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 limit our ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to our ownership changes and those of BPS.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2011 and/or changes in our ownership that resulted from our follow-on offering or our ATM Offering have caused or will cause another ownership change to occur. Any such change could result in significant limitations on some or all of our net operating loss carryforwards and other tax attributes.

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

Income tax expense was \$0 for the three months ended June 30, 2014 and 2013. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

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

We have prepared our financial statements in accordance with United States generally accepted accounting principles. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. We have reviewed our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

Our Annual Report on Form 10-K for the year ended December 31, 2013, discusses our most critical accounting policies. Since December 31, 2013, there have been no material changes in the critical accounting policies discussed in the 2013 Annual Report.

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

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

## Results of Operations

### Comparison of the Three Months Ended June 30, 2014 and 2013

*Revenues.* Revenues for the three months ended June 30, 2014 were \$212,000, decreasing from \$232,000 for the same period in 2013. The decrease in revenue of \$20,000 was due to a decrease in billings by BPS under various DOD contracts and NIH grants.

*Research and Development Expenses.* Research and development expenses for the three months ended June 30, 2014 were \$6.5 million, increasing from \$5.0 million for the same period in 2013. The \$1.5 million increase was due to an increase of \$798,000 in clinical, contract manufacturing, and consulting expenses, accompanied by a \$735,000 increase in personnel-related expenses, and offset by a \$45,000 decrease in equipment and supplies. The increase in clinical, contract research and manufacturing and consulting fees is primarily attributable to the completion of certain research services agreements, and the increase in personnel-related expense is attributable to both increases in headcount and compensation levels, including share-based compensation.

*General and Administrative Expenses.* General and administrative expenses for the three months ended June 30, 2014 were \$2.9 million, increasing from \$2.3 million for the same period in 2013. The \$600,000 increase was primarily due to an increase of \$228,000 in legal and consulting fees, accompanied by an increase of \$187,000 in software subscriptions and other expenses, an increase of \$148,000 in share-based compensation expense, and an increase of \$37,000 in supplies and occupancy expenses.

*Net Loss.* Net loss for the three months ended June 30, 2014 was 9.2 million, increasing from 7.1 million for the same period in 2013 due to the changes in research and development and general and administrative expenses discussed above. The weighted average common shares outstanding for the first quarter 2014 were 27.9 million, resulting in a loss per share of \$0.33, as compared to 25.6 million and \$0.28 per share for first quarter 2013. The increase in the number of weighted average common shares outstanding was primarily attributable to shares issued in our ATM Offering during the fourth quarter of 2013 and the first quarter of 2014.

### Comparison of the Six Months Ended June 30, 2014 and 2013

*Revenues.* Revenues for the six months ended June 30, 2014 were \$546,000, increasing from \$534,000 for the same period in 2013. The increase in revenue of \$12,000 was due to an increase in billings by BPS under various DOD contracts and NIH grants.

*Research and Development Expenses.* Research and development expenses for the six months ended June 30, 2014 were \$12.9 million, increasing from \$11.4 million for the same period in 2013. The \$1.5 million increase was due to an increase of \$1.6 million in personnel-related expenses, offset by a \$108,000 decrease in contract research and manufacturing and consulting fees. The decrease in contract research and manufacturing and consulting fees is primarily attributable to the completion of certain contract research services agreements, and the increase in personnel-related expense is attributable to both increases in headcount and compensation levels, including share-based compensation.

*General and Administrative Expenses.* General and administrative expenses for the six months ended June 30, 2014 were \$6.1 million, increasing from \$4.3 million for the same period in 2013. The \$1.8 million increase was primarily due to an increase of \$1.0 million in personnel-related expenses, including share-based compensation expense, accompanied by an increase of \$350,000 in legal and consulting fees, an increase of \$310,000 in software subscriptions, marketing and other expenses, and increases of \$120,000 in travel expense, and an increase of \$60,000 in supplies and occupancy.

**Net Loss.** Net loss for the six months ended June 30, 2014 was 18.4 million increasing from 15.0 million for the same period in 2013 due to the changes in research and development and general and administrative expenses discussed above. The weighted average common shares outstanding for the first six months of 2014 were 27.7 million, resulting in a loss per share of \$0.66, as compared to 24.7 million and \$0.61 per share for first six months of 2013. The increase in the number of weighted average common shares outstanding was primarily attributable to shares issued in our ATM Offering during the fourth quarter of 2013 and the first quarter of 2014.

## Liquidity and Capital Resources

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

Since our IPO, we have funded our operations principally through public offerings of common stock. On November 16, 2011, we received proceeds, net of offering costs, of \$37.6 million from the issuance of 6.2 million shares of common stock in our IPO. On February 4, 2013, we received proceeds, net of offering costs, of \$49.0 million from the issuance of 4.6 million shares of common stock in our follow-on offering. We entered into a Sales Agreement with Cantor Fitzgerald & Co., dated as of September 5, 2013, or the Cantor Agreement, under which we may sell up to \$60.0 million of our common stock in one or more placements at prevailing market prices. Any such sales would be effected pursuant to our registration statement on Form S-3 (333-185721), declared effective by the SEC on January 4, 2013. As of June 30, 2014, we had sold 1.8 million shares under the ATM Offering, raising a total of \$45.0 million in net proceeds. Subsequent to March 31, 2014 and through the date of this filing, we sold no additional shares of common stock under the ATM Offering.

As of June 30, 2014, we had cash, cash equivalents and certificates of deposit of approximately \$77.1 million. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

### Sources and Uses of Cash (in thousands)

	Six Months Ended June 30,	
	2014	2013
Net cash used in operating activities	\$ (13,103)	\$ (11,477)
Net cash (used in) provided by investing activities	(297)	971
Net cash provided by financing activities	28,970	49,295
Net increase in cash and cash equivalents	\$ 15,570	\$ 38,789

For the six months ended June 30, 2014 and 2013, we used cash of \$13.1 million and \$11.5 million for our operating activities, respectively. The cash used by operating activities in the six months ended June 30, 2014 primarily resulted from our net loss of \$18.4 million, offset by non-cash expenses of \$4.1 million (primarily share-based compensation and depreciation) and offset by changes in operating assets and liabilities of \$1.2 million. The cash used by operating activities in the six months ended June 30, 2013 primarily resulted from our net loss of \$15.0 million, offset by non-cash expenses of \$2.5 million, and offset by changes in operating assets and liabilities of \$1.1 million.

For the six months ended June 30, 2014 and 2013, our investing activities used cash of \$297,000 and provided cash of \$971,000, respectively. The cash used by investing activities in the six months ended June 30, 2014 was a result of the purchase of fixed assets of \$297,000. The cash provided by investing activities in the six months ended June 30, 2013 was primarily a result of the sale of certificates of deposit of \$1.2 million, offset by the purchase of equipment of \$274,000.

For the six months ended June 30, 2014 and 2013, our financing activities provided \$29.0 million and \$49.3 million, respectively. 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 of \$27.5 million, accompanied by the exercise of stock options of \$1.7 million, offset by the repurchase of common stock of \$182,000. The cash provided by financing activities in the six months ended June 30, 2013 was primarily due to the sale and issuance of common stock of \$49.4 million.

## **Operating Capital Requirements**

We anticipate that we will continue to generate significant operating losses in the future 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. Including the funds received from our follow-on public offering in February 2013 and the funds received to date from our ATM Offering, we believe that we have sufficient cash and cash equivalents and certificates of deposit to fund our operations well into 2015, although not through commercialization and launch of revenue producing products.

We may seek to sell additional equity securities, which may include sales of our common stock pursuant to the Cantor Agreement, if any, or otherwise, or debt securities or to 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 are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

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

- the scope, progress, results and costs of clinical trials for our product candidates, and discovery and development activities related to new product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales, distribution and facilities and occupancy 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 partnerships, licensing or other arrangements and the financial terms of such agreements;
- whether, and to what extent, we are required to repay our outstanding government provided loans;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

## **Contractual Obligations and Commitments**

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

## **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, 2014 and December 31, 2013, we had cash and cash equivalents and certificates of deposit of \$77.1 million and \$61.5 million, respectively, consisting of money market funds and bank certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of 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, 2014. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2014, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

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

We implemented a new enterprise resource planning, or ERP, system in the third quarter of 2013. As of June 30, 2014, the ERP system was used for certain manufacturing and finance purposes and we expect the ERP system to be used for other manufacturing and finance functions in 2014. The new ERP system did not eliminate any existing controls over financial reporting. In addition, the ERP system can support internal controls over some items that our previous accounting system did not support.

With the exception of the new ERP system, 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 resected pancreatic cancer. If we fail to complete, or fail to demonstrate safety and efficacy in clinical trials, fail to obtain regulatory approval or fail to successfully commercialize algenpantucel-L, our business would be harmed and the value of our securities would likely decline.***

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

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

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

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

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

In particular, there have been no control groups in our clinical trials completed to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of algenpantucel-L, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared. As a result, we are studying algenpantucel-L in combination with the current standard-of-care in direct comparison to the current standard-of-care alone in the same trial and will need to show a statistically significant benefit when added to the current standard-of-care in order for algenpantucel-L to be approved as a marketable drug. Patients in our Phase 3 study who do not receive algenpantucel-L may not have results similar to patients studied in the other studies we have

used for comparison to our Phase 2 studies. If the patients in our Phase 3 study who receive standard-of-care without algenpantucel-L have results which are better than the results predicted by the other large studies, we may not demonstrate a sufficient benefit from algenpantucel-L to allow or convince the FDA to approve it for marketing.

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

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

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

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

***Our Special Protocol Assessment, or SPA, with the FDA relating to our algenpantucel-L IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) Phase 3 clinical trial does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.***

The protocol for our algenpantucel-L IMPRESS Phase 3 clinical trial was reviewed by the FDA under its SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a Biologics License Application, or BLA, and provides an agreement that the study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval. The FDA retains the right to require additional Phase 3 testing, and we cannot be certain that the design of, or data collected from the IMPRESS Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of algenpantucel-L for the treatment of patients with pancreatic cancer, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition, the survival rates, duration of response and safety profile required to support FDA approval are not specified in the IMPRESS Phase 3 clinical trial protocol and will be subject to FDA review. Although the SPA agreement calls for review of interim data at certain times prior to completion, there is no assurance that any such review, even if such interim data are positive, will result in early approval. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the IMPRESS Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the SPA agreement, how it will interpret the data and results from the IMPRESS Phase 3 clinical trial, or whether algenpantucel-L will receive any regulatory approvals as a result of the SPA agreement or the IMPRESS Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for algenpantucel-L for the treatment of patients with pancreatic cancer.

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

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle including by allowing Investigational New Drug applications

to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions, and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

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

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

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- enrollment in and conduct of our clinical trials may be adversely affected by competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- we may experience delays in achieving study endpoints and completing data analysis for a trial.

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

Moreover, our development costs will increase if we are required to complete additional or larger clinical trials for the HyperAcute product candidates, indoximod, or other IDO pathway inhibitor product candidates such as NLG919, prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize the HyperAcute product candidates, indoximod, NLG919 or other future product candidates will be adversely affected.

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

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

- severity of the disease under investigation;
- design of the trial protocol;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;

- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

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

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

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

We have discussions with and obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA. Should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

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

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

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

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

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

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

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;

- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our HyperAcute product candidates, indoximod, NLG919 and other product candidates could take a significantly longer time to gain regulatory approval for any additional indications than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating the commercialization of our HyperAcute product candidates, indoximod, NLG919 and other product candidates for additional indications.

***Some of our product candidates have been or in the future may be studied in clinical trials co-sponsored by the National Cancer Institute, or NCI, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.***

Our indoximod product candidate has been studied in two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying our indoximod product candidate in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of our dorgenmeltuceL-L (HyperAcute Melanoma) product candidate in support of a Phase 2 investigator-initiated clinical trial. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

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

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

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

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

***Even if approved, the HyperAcute product candidates, indoximod, NLG919 or any other product we may commercialize and market may be later withdrawn from the market or subject to promotional limitations.***

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

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

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

To do this effectively, we must:

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

We plan to increase our manufacturing capacity, which may include negotiating and entering into arrangements for third-party contract manufacturing for some or all of our commercial manufacturing requirements, and seek FDA approval for our production process simultaneously with seeking approval for the marketing and sale of our algenpantucel-L. Should we not receive timely approval of our production process, our ability to produce the immunotherapy products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

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

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

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic 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 that have contingently agreed to join us do not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our facilities are located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. 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. On June 19, 2014, we entered into the WuXi Agreement, under which we granted WuXi a non-exclusive right to use certain of our starting materials and confidential information for the commercial manufacturing of cell material for the production of algenpantucel-L. We will incur significant expense under the WuXi Agreement, and our commercial relationship with WuXi may not result in the manufacture of algenpantucel-L to the required quality standards or in quantities or at a cost that allows any future commercial sales to be profitable or commercially viable for many reasons, including the following:

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

We may develop additional or alternative manufacturing capacity by expanding our current facilities, by entering into additional third-party contract manufacturing arrangements, or by some combination of the foregoing. Expanding our current facilities would require substantial additional funds and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing facilities that are sufficient to produce materials for additional later-stage clinical trials or commercial use. Contracting for additional third-party commercial manufacturing would require expertise and qualified personnel to manage the added complexity of such additional relationships and regulatory compliance at multiple manufacturing sites operated by different third-parties and may further increase our expenses related to, and decrease our direct control over, procuring a sufficient supply of our product candidates for commercial sale.

If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with WuXi or other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business,

financial condition and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of each BLA and each New Drug Application, or NDA, on a timely basis and must adhere to Good Laboratory Practice, or GLP and cGMP regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA approval of the products will not be granted.

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

All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including WuXi, our existing contract manufacturer for indoximod and the components used in the HyperAcute product candidates, our contract manufacturer for NLG919, and any contract manufacturer that we may use in the future for manufacturing related to clinical trials or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of the HyperAcute product candidates, indoximod, NLG919 or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of the HyperAcute product candidates, indoximod, NLG919 or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. In addition, to the extent that we rely on foreign contract manufacturers, as we do currently for NLG919, we are or will be subject to additional risks including the need to comply with export and import regulations.

***We currently rely on relationships with third-party contract manufacturers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates in the near-term. The loss of any of these manufacturers, some of which are our only current source for components of our product candidates, or delays or problems in the supply or manufacture of components of our product candidates, could materially and adversely affect our business, financial condition and results of operations.***

We intend to rely upon contract manufacturers for indoximod, NLG919, and for components of or finished HyperAcute product candidates, including algenpantucel-L, for commercial sale if any are approved for sale. In addition, we currently rely on a contract manufacturer for supply of NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of antigen, components of or finished HyperAcute product candidates, indoximod or NLG919. This could delay or reduce commercial sales and materially harm our business. We do not currently have experience with the manufacture of products at commercial scale, or the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to manufacture products at commercial scale or to negotiate and enter into relationships with third-party contract manufacturers. Any prolonged delay or interruption in the operations of our facilities or our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of drug substances could delay our clinical trials, increase our costs, damage our reputation and cause us to lose revenue and market share if we are unable to timely meet market demand for any products that are approved for sale.

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

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

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

Our current manufacturing facility contains highly specialized equipment and utilizes complicated production processes developed over a number of years, which would be difficult, time-consuming and costly to duplicate or may be impossible to duplicate. Any prolonged disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture product candidates for clinical testing on our own and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. We may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

We have experienced bacterial and 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 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 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 \$9.5 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have also outsourced elements of our information technology infrastructure, and as a result we manage a number of third party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber attacks. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology

systems, such measures may not prevent the adverse effect of such events. Significant disruptions of our information technology systems or breaches of data security could adversely affect our business.

## **Risks Relating to Regulation of Our Industry**

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

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

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

Regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate. To date, the FDA has approved only one active cellular cancer immunotherapy product, even though several have been, and currently are in, clinical development. Further, even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer.

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

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

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

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

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

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

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

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

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

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

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

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

laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

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

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. We expect to face pricing pressure globally from managed care organizations, institutions and government agencies and programs, which could negatively affect the sales and profit margins for our HyperAcute product candidates, indoximod, NLG919 or any other 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.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies.

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

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

elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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

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

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

## **Financial Risks**

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

We are not profitable and have incurred significant net losses in each year since our inception, including net losses of \$31.2 million, \$23.3 million and \$18.1 million for the years ended December 31, 2013, 2012 and 2011, respectively and a net loss of 18.4 million for the six months ended June 30, 2014. As of June 30, 2014, we had a deficit of \$154.4 million. 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 our commercialization activities and our discovery and research activities, including the Phase 2 and Phase 3 clinical development of the HyperAcute product candidates, the Phase 2 clinical development of indoximod, and the Phase I development of NLG919.

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

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

Development of our HyperAcute product candidates, indoximod, NLG919 and any other product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, 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 submit);
- 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, including the proceeds from our follow-on public offering that closed on February 4, 2013, and proceeds received to date from our ATM Offering, if any, will allow us to fund our operating plan well into 2015, although not through commercialization and launch of revenue producing products. 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.

***We have a forgivable loan that may have to be repaid if we do not achieve job creation goals.***

In March 2010, we entered into a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce that requires us to create or retain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2015, we have failed to create or retain at least 150 full-time jobs in Ames, Iowa, we will be required to repay approximately \$3,100 per job not created or retained. As of June 30, 2014, we had created or retained an aggregate of 101 full-time jobs in Ames, Iowa. On July 25, 2014, we received \$100,000 after completing certification regarding the creation of a threshold level of jobs, as part of a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders.

We have not yet met all the job creation requirements of the City of Ames loan. If we cannot or do not comply with this and all other requirements under this loan, we may be obligated to partially repay principal and interest on this loan.

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

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

Through our subsidiary, BioProtection Systems Corporation, or BPS, we also have an ongoing contract with the United States Department of Defense and pending applications with the National Institutes of Health and the Department of Defense. 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.***

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

### **Risks Relating to Competition**

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

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

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

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

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

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

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

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

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

Research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, indoximod, NLG919 or our other potential products obsolete even before they begin to generate any revenue. If the FDA approves the commercial sale of any of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval but cannot compete effectively in the marketplace.

Our biodefense product candidates face significant competition for United States government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. 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 addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

***Our 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 the HyperAcute product candidates, indoximod, NLG919 or any of our other potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our future products, if successfully developed, will compete with a number of traditional products and immunotherapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution

restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third party payors.

### **Risks Relating to Our Arrangements with Third Parties**

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

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

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

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

To successfully commercialize the HyperAcute product candidates, indoximod, NLG919 or any other 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. Such collaborations are complex and any potential discussions may not result in a definitive agreement for many reasons. For example, whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the potential market for the HyperAcute product candidates and indoximod, the costs and complexities of manufacturing and delivering the HyperAcute product candidates, indoximod, NLG919 or any other 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 the HyperAcute product candidates, indoximod, NLG919, or any other potential product is necessary and were unable to enter into such a collaboration on acceptable terms, we might elect to delay or scale back the commercialization of the HyperAcute product candidates, indoximod, NLG919, or any other 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, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected financial resources, efforts or required expertise in developing the physical resources and systems necessary to successfully commercialize the HyperAcute product candidates, indoximod, NLG919, or any other 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 HyperAcute product candidates, indoximod, NLG919, or any other potential product reach their full potential;
- disputes may arise between us and a collaborator that delay the commercialization or adversely affect its sales or profitability of the HyperAcute product candidates, indoximod, NLG919, or any other potential product; or
- the collaborator may independently develop, or develop with third parties, products that could compete with the HyperAcute product candidates, indoximod, NLG919, or any other potential product.

If we enter into one or more collaborations for our HyperAcute product candidates, indoximod, NLG919, or any of our other product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates that are difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the HyperAcute product candidates, indoximod, NLG919, or any other potential product may have the right to terminate the collaboration at its discretion. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or require us to delay or scale back the commercialization efforts. The occurrence of any of these events could adversely affect the commercialization of the HyperAcute product candidates, indoximod, NLG919, or any other potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

***We may explore strategic collaborations that may never materialize or may fail.***

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

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

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

## **Risks Relating to Protecting Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

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

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

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

### **Risks Relating to Our Exposure to Litigation**

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

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

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

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;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- actual and anticipated fluctuations in our quarterly operating results;
- the financial projections we may provide to the public, 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, 2014, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 44.9% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after June 30, 2014. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

***A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Certain holders of outstanding shares of our common stock that have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Stock Market, or NASDAQ. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to publish a report by our management on our internal control over financial reporting. To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan. Despite our effort, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, our ability to pay cash dividends is currently prohibited by the terms of one of our debt financing arrangements, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common

stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

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

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

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

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

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

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

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

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

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

Based on Section 382 ownership change analyses, we believe that, from its inception through December 31, 2011, 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 limit NewLink's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective ownership changes of NewLink and our subsidiary.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2011 and/or changes in our ownership that resulted from our follow-on offering or our ongoing ATM Offering have caused or will cause another

ownership change to occur, and the conclusions will depend on information that currently may not be available to us. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

Additional ownership changes may occur in the future as a result of events over which we will have little or no control, including purchases and sales of our equity by our 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of our stock or certain changes in the ownership of any of our 5% stockholders.

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

***We implemented a new accounting software, or ERP, system in the third quarter of 2013, and we may experience unforeseen difficulties or delays related to implementation of the new system.***

We plan to implement additional purchasing processes in the ERP system during 2014. If we encounter unforeseen difficulties in using the system or implementing additional processes, we could experience delays in financial reporting, weaknesses in our internal controls or unanticipated expenses.

**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 5, 2014

By:           /s/ Gordon H. Link, Jr.

Gordon H. Link, Jr.

Chief Financial Officer and Secretary

(Principal Financial Officer)

Date: August 5, 2014

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	Development and Manufacturing Terms and Conditions by and between the Company and WuXi AppTec, Inc. dated June 19, 2014				X
10.2	Development and Process Transfer Program Leading to Commercial Manufacturing for algenpantucel-L HyperAcute Pancreas by and between the Company and WuXi AppTec, Inc. dated as of June 19, 2014				X
10.3	† Amendment to 2010 Non-Employee Directors' Stock Award Plan				X
10.4	† Form of Restricted Stock Unit Award Agreement under the 2010 Non-Employee Directors' Stock Award Plan, as amended				X
10.5	† Form of Restricted Stock Unit Grant Notice under the 2010 Non-Employee Directors' Stock Award Plan, as amended				X
10.6	† Form of Restricted Stock Unit Award Agreement under the 2009 Equity Incentive Plan, as amended				X
10.7	† Form of Restricted Stock Unit Grant Notice [Four Year Annual Vesting] under the 2009 Equity Incentive Plan, as amended				X
10.8	† Form of Restricted Stock Unit Grant Notice [Immediately Vested] under the 2009 Equity Incentive Plan, as amended				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.

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



## CELL THERAPY DEVELOPMENT, MANUFACTURING AND/OR TISSUE PROCESSING TERMS AND CONDITIONS

BETWEEN

WuXi AppTec, Inc. and NewLink Genetics Corporation

This Development and Manufacturing Terms and Conditions (the "**Agreement**") is made and entered into as of the date of the last signature on the signature page hereto (the "**Effective Date**") by and between WuXi AppTec, Inc., a corporation organized under the laws of Delaware with offices located at 4751 League Island Blvd., Philadelphia, PA 19112 ("**WuXi AppTec**"), and NewLink Genetics Corporation, a company organized under the laws of Delaware with offices located at 2503 South Loop Drive, Suite 5100, Ames, IA 50010 and Affiliates ("**Customer**"). Customer and WuXi AppTec are referred to herein individually as a "**Party**" and collectively as the "**Parties**".

The Parties hereto agree as follows:

- 1) **Term/Termination.** From time to time, Customer may submit to WuXi AppTec written work orders ("**Work Orders**") for services ("**Services**") to be performed by WuXi AppTec under this Agreement. Upon mutual agreement and execution of a Work Order by both Parties, such Work Order shall be incorporated into this Agreement. This Agreement shall become effective as of the Effective Date and will expire on the later of (a) [\*] years from the Effective Date or (b) the completion of all Services under the last Work Order executed by the Parties prior to the [\*] anniversary of the Effective Date. The Agreement may be extended by mutual agreement of the Parties or earlier terminated in accordance with Section 11.
- 2) **Product.** "**Product**" covered under this Agreement means all or any part of the product manufactured (including any sample thereof), the particulars of which are listed in the relevant Work Orders attached hereto.
- 3) **Special/Custom Equipment.** In the event special or custom equipment is required for the manufacture of Product, Customer shall provide WuXi AppTec with such equipment (the "**Equipment**") to be used to manufacture the Product which Equipment is listed in the relevant Work Orders attached hereto. The Equipment shall remain Customer's property at all times and WuXi AppTec shall use the Equipment solely to perform the Services for Customer under this Agreement and the relevant Work Order and for no other purpose. WuXi AppTec shall maintain and keep the Equipment in proper working order and secure and safe from loss and damages. WuXi AppTec shall be liable to Customer for loss and damage to the Equipment while in its possession (ordinary wear and tear excepted). In the event that any item of Equipment reaches the end of such item's useful life due to ordinary wear and tear from the performance of the Services hereunder, then upon request by WuXi AppTec, Customer shall at Customer's option either repair or replace such item at Customer's expense.
- 4) **Procurement, Processing and Packaging.**

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

- (a) Customer shall provide WuXi AppTec with the [\*] for WuXi AppTec to perform the Services and to manufacture the Product, and WuXi AppTec shall procure other starting materials, at [\*] cost and as set forth in the relevant Work Order (together with the [\*] provided by Customer, the "**Starting Material**"), for subsequent processing into Product in accordance with the Product Specifications (as defined in Section 4(e)). Customer shall supply WuXi AppTec with relevant information and full details of any hazards relating to Starting Material, their storage and use. Upon review of this information, the Starting Material and any Customer know-how, procedures and other relevant information necessary for WuXi AppTec to process Starting Material into Product shall be provided to (or procured by, as applicable) WuXi AppTec. All Starting Material delivered to WuXi AppTec shall be shipped by a reputable shipping company selected by [\*] at WuXi AppTec's facility in Philadelphia, Pennsylvania or such other location as the Parties may agree from time to time ("**WuXi AppTec Plant**"). [\*] shall bear all risk of loss prior to delivery at WuXi AppTec Plant. WuXi AppTec will inspect the Starting Material as soon as practical after receipt and promptly inform Customer of any damage or loss. Customer shall retain title to the Starting Materials at all times, but risk to undamaged Starting Material shall pass from [\*] after [\*]. WuXi AppTec shall maintain and keep Starting Materials secure and safe from loss and damage, and shall be liable to Customer for the replacement of any Starting Materials lost or damaged while [\*]. [\*] shall pay all shipping or similar charges (including insurance and tax, if any) applicable to [\*] delivery of Starting Material pursuant to this Section 4(a).
- (b) Customer hereby grants WuXi AppTec the non-exclusive right to use the Starting Material and any Confidential Information (as defined in Section 10) supplied by Customer for the sole purpose of performing the Services for Customer under the Agreement and the relevant Work Order. WuXi AppTec hereby undertakes not to use the Starting Material or any Confidential Information of Customer for any other purpose.
- (c) WuXi AppTec may in its sole discretion amend or modify its SOP manual and or individual policies and procedures, except that WuXi AppTec shall not make any such changes that affect the specifications for the Services and Product outlined by Customer under this Agreement or set forth in the applicable Work Order without Customer's express prior written consent, unless the changes are required by state/federal regulations, in which case WuXi AppTec shall promptly notify Customer of any such required change.
- (d) Customer agrees that its contracts and certification relating to the logistical screening and isolation of Starting Materials shall be in compliance with the current rules, regulations, standards and interpretations of the Food and Drug Administration (the "**FDA**") and agrees to use its [\*] efforts to comply with any future changes in the rules, regulations, standards and interpretations of the FDA as appropriate.
- (e) WuXi AppTec shall: (i) perform the Services, including processing Starting Material provided by Customer into the Product, in accordance with all applicable laws and regulations (including without limitation cGMP), the terms of this Agreement and the applicable Work Order, including the Product specifications set forth in Work Orders or as agreed to in writing by the Parties and attached hereto under a separate Exhibit (the "**Product Specifications**"), which Product Specifications may be amended or modified by mutual written agreement of the Parties; (ii) package and label the Product in accordance with Section 7 below; and (iii) deliver the Product to Customer or such other location designated by Customer in accordance with Section 7 below. WuXi AppTec will process Starting Material into the Product in a timely manner as agreed upon by the Parties.
- (f) WuXi AppTec represents and warrants that: (i) the Services will be performed in compliance with the terms and conditions of this Agreement, the applicable Work Order and all applicable laws and regulations (including without limitation cGMP); (ii) the Product delivered will comply with the Product Specifications; (iii) the Services performed by WuXi AppTec hereunder will not infringe or misappropriate any intellectual property rights of any third party. In the event that any Service or

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Product provided by WuXi AppTec fails to comply with any of the foregoing warranties, WuXi AppTec shall, at Customer's election, promptly [\*], or promptly [\*]. Notwithstanding the foregoing, the Parties acknowledge and agree that because of the [\*] of the [\*], there is no guarantee that a [\*] and therefore WuXi AppTec shall not be responsible for [\*], provided that (a) the [\*] and (b) the Services and Products provided by WuXi AppTec otherwise comply with the foregoing warranties.

- (g) EXCEPT AS EXPRESSLY SET FORTH HEREIN, WUXI APPTec MAKES NO PRODUCT WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THE SOLE AND EXCLUSIVE REMEDIES OF CUSTOMER FOR BREACH OF A PRODUCT WARRANTY SHALL BE [\*].
- (h) WuXi AppTec shall not be liable for any claim of Product non-conformance or breach of warranty unless such claim is submitted in writing by Customer within [\*] following the date Services were completed or the date of the breach giving rise to such claim, whichever is later.

## 5) Delivery/Shipping.

- (a) Product shall be delivered [\*], which means (a) when WuXi AppTec [\*] at [\*] and (b) risk and title to Product pass to Customer upon [\*]. Transportation of Product, whether or not under any arrangements made by [\*] on behalf of [\*], shall be made at the sole risk and expense of [\*].
- (b) Unless otherwise agreed or set forth in the applicable Work Order, WuXi AppTec shall package and label Product for delivery in accordance with its standard operating procedures and in accordance with required shipping conditions. It shall be the responsibility of Customer to inform WuXi AppTec in writing in advance of any special packaging and labeling requirements for Product. All [\*] costs and expenses of whatever nature incurred by WuXi AppTec in complying with such special requirements [\*] shall be [\*] the price for Services.
- (c) If [\*], WuXi AppTec will [\*] arrange the transportation of Product from WuXi AppTec Plant to the destination indicated by Customer together with insurance coverage for Product in transit at its invoiced value. All [\*] costs and expenses of whatever nature incurred by WuXi AppTec in arranging such transportation and insurance [\*] shall be [\*] the price for Services.
- (d) Where WuXi AppTec has made arrangements for the transportation of Product, Customer shall diligently examine the Product as soon as practicable after receipt. Notice of all claims (time being of the essence) arising out of: (1) Visible damage to or total or partial loss of Product in transit shall be given in writing to WuXi AppTec and the carrier within [\*] of receipt by Customer; or (2) Non-delivery shall be given in writing to WuXi AppTec within [\*] of receipt by Customer of WuXi AppTec's dispatch notice.
- (e) Customer shall make damaged Product and associated packaging materials available for inspection and shall comply with the reasonable requirements of any insurance policy covering the Product for which notification has been given by WuXi AppTec to Customer. [\*] shall offer [\*] all reasonable assistance in pursuing any claims arising out of the transportation of Product.
- (f) Promptly following receipt of Product or any sample thereof, Customer may carry out any of the tests outlined or referred to in the Product Specifications. If such tests show that the Product fails to meet the Product Specifications, Customer shall have the right to reject such Product by giving WuXi AppTec written notice thereof within [\*] from [\*]. In addition, except where the shelf life of the Product has expired, Customer shall have the right to reject the Product if Customer later discovers any non-obvious defect not reasonably susceptible to discovery within the [\*] notice period and provides notice thereof to WuXi AppTec within [\*] after [\*]. Customer shall return such non-conforming Product

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to WuXi AppTec's premises, at [\*] expense, for further testing. If data from such further testing is inconclusive as to whether the returned Product fails to meet the Product Specifications (for example, when compared to Product retains) or whether such failure is due to acts or omissions of Customer or any third party after delivery, the Parties may submit the Product in question and any retains to a mutually agreed independent laboratory for testing. The decision of such independent laboratory shall be final and binding upon the Parties, and the Party against whom such independent laboratory rules shall bear the cost of such testing. If the Product returned to WuXi AppTec fails to meet Product Specifications and such failure is not due to the acts or omission of [\*] or [\*], or is due to any act or omission of [\*], then WuXi AppTec shall refund that part of the price that relates to the production of such Product.

**6) Consideration.**

- (a) Customer shall pay the price in accordance with the price detailed in Work Orders attached hereto for Services that are performed in compliance with the Product Specifications or other agreed-upon terms.
- (b) Payment shall be made in accordance with Work Orders attached hereto. Unless otherwise indicated in writing by WuXi AppTec, all prices and charges are [\*] of any applicable taxes, levies, duties and fees of whatever nature imposed by or under the authority of any government or public authority, which shall be paid by [\*] (other than [\*]). Undisputed payment must be made within [\*] of receipt by Customer of a correct invoice. Payment shall be made without deduction, deferment, set-off, lien or counterclaim of any nature.
- (c) In the event of a default of payment on due date: (1) Interest shall accrue on any amount overdue at the annual rate of [\*] above the prime rate of interest published from time to time in the Wall Street Journal (or similar successor rate), interest to accrue on a day to day basis both before and after judgment; and (2) WuXi AppTec shall, at its sole discretion and without prejudice to any other of its accrued rights, be entitled to terminate this Agreement in accordance with Section 11(a)(ii).

**7) Quality Assurance.**

WuXi AppTec shall permit Customer and its representatives to inspect its facilities and review its staff for the purpose of quality assurance. Any such inspections shall be performed upon reasonable notice during normal business hours. Customer shall: (i) identify the staff that will perform such inspection; (ii) maintain as confidential any information or observation made as part of such inspection; (iii) instruct such staff to conduct themselves in an appropriate manner; (iv) not unnecessarily interfere with operations; and (v) as applicable, provide a written report to WuXi AppTec of the inspection. WuXi AppTec will provide Customer with copies of applicable documentation related to production records, audit reports and FDA inspection reports. WuXi AppTec shall promptly notify Customer of any inspection of the WuXi AppTec Plant by any regulatory agency that relates to the Services or Product. Unless prohibited by applicable law, Customer shall have the right to be present at any such inspection, and WuXi AppTec shall provide Customer with copies of all correspondence with such regulatory agency relating thereto. WuXi AppTec shall take all reasonable actions requested by Customer or the regulatory agency to cure any deficiencies noted during such inspection.

**8) Regulatory Matters.**

- (a) Customer shall, at its expense, obtain and maintain all permits, licenses, clearances and approvals from the FDA and other regulatory agencies as are necessary or appropriate for the distribution of the Products.

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- (b) Each Party will notify the other Party promptly upon receipt of information indicating that any of the Products may be subject to a recall, field corrective action or other regulatory action with respect to a Product taken either by virtue of applicable federal, state, foreign or other law or regulation or good business judgment (a "**Remedial Action**"). Customer shall be responsible for determining the necessity of conducting any Remedial Action and WuXi AppTec shall cooperate in gathering and evaluating such information as is reasonably necessary for Customer to make such determination. In the event Customer determines that a Remedial Action should be commenced or a Remedial Action is required by any governmental authority having jurisdiction over the matter, Customer shall be responsible for the control and coordination of all efforts necessary to conduct such Remedial Action and shall keep WuXi AppTec reasonably informed regarding the status of such Remedial Action. [\*] shall be responsible for the cost and expense of the Remedial Action unless the Remedial Action results from [\*], in which case [\*] shall be responsible and shall reimburse [\*] for the cost and expense of such Remedial Action.
- (c) Each Party will comply with the applicable provisions of the Adverse Reaction Reporting systems, including the requirements of 21 CFR Part 1270, and each Party will cooperate with the other Party for the efficient compliance therewith. WuXi AppTec agrees to notify Customer promptly upon receipt from any customer of any complaint or Adverse Reaction Report relating to the Products. Customer shall investigate, and WuXi AppTec shall reasonably cooperate in any investigation of, such complaint or Adverse Reaction Report, and Customer will keep WuXi AppTec reasonably informed regarding the findings of such investigation.

## 9) Insurance and Indemnification.

- (a) Customer shall indemnify and hold harmless WuXi AppTec, its officers, directors, agents and employees from and against any and all losses, costs, damages and/or expenses (including, without limitation, reasonable costs of counsel), incurred by any such indemnitee as a result of or in connection with any claim by any third party 1) for injury (physical, emotional, psychological or other) or death of any person or physical damage to any property arising out of [\*], provided such claim, injury, death or property damage is not the result of WuXi AppTec's [\*] or breach of this Agreement in carrying out its obligations under this Agreement or any Work Order, or 2) alleging WuXi AppTec's [\*], or Customer's intellectual property rights that are [\*], infringes any rights (including, without limitation, any intellectual or industrial property rights) vested in any third party (whether or not the Customer knows or ought to have known about the same). In the event a third party claim is asserted against WuXi AppTec for which indemnification is required hereunder, WuXi AppTec shall give Customer prompt written notice thereof. WuXi AppTec shall cooperate with Customer, at Customer's cost and expense, in the defense of any such claim. Customer shall have the sole right to defend and/or settle such a claim, including selecting counsel of its choice. Costs, expenses and fees incurred by WuXi AppTec and as to which WuXi AppTec has a right of indemnification hereunder shall be periodically reimbursed by Customer as incurred.
- (b) WuXi AppTec shall indemnify and hold Customer harmless against all claims, actions, costs, expenses (including, without limitation, court costs and reasonable attorney's fees) or other liabilities (collectively, "**Losses**") whatsoever to, from or in favor of third parties, to the extent such Losses are caused or contributed to by 1) WuXi AppTec's performance of the Services (except to the extent resulting from WuXi AppTec's use of [\*]); and/or 2) the [\*] or breach of this Agreement of WuXi AppTec or any of its employees or agents in the performance of Services. WuXi AppTec's liability to indemnify Customer shall be reduced to the extent that such Losses were caused or contributed to by the [\*] or breach of this Agreement by Customer. In the event a third party claim is asserted against Customer for which indemnification is required hereunder, Customer shall give WuXi AppTec prompt written notice thereof. Customer shall cooperate with WuXi AppTec, at WuXi AppTec's cost and expense, in the defense of any such claim. WuXi AppTec shall have the sole right to defend and/or settle such a claim, including selecting counsel of its choice. Costs, expenses and fees

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incurred by Customer and as to which Customer has a right of indemnification hereunder shall be periodically reimbursed by WuXi AppTec as incurred.

- (c) Each Party shall maintain a separate policy or policies of insurance in the amount of at least [\*] per occurrence and [\*] in the aggregate for insuring against liability which may be imposed arising out of its acts or omissions to include: 1) comprehensive general liability providing coverage for personal injury, bodily injury, property damage; and 2) professional liability. In addition, Customer shall maintain product liability insurance in the aggregate of at least [\*]. As soon as practicable following the execution of this Agreement, each Party shall cause its insurer(s) to list the other Party as an additional insured on the insurance policies required hereby and shall deliver to the other Party a certificate(s) of insurance Party evidencing the applicable coverage(s).
- (d) WuXi AppTec's sole liability for any loss or damage suffered by Customer as a result of any breach of the Agreement or of any other liability of WuXi AppTec in respect of the Services conducted under this Agreement or any Work Order (including without limitation the production and/or supply of the Product) shall be limited to [\*] in an amount not exceed [\*]. This limitation shall not apply in the event such damages were caused by the gross negligence or willful misconduct (including, without limitation, intentional breach, non-performance or delay) of WuXi AppTec, or WuXi AppTec's breach of [\*] set forth in Section [\*] or its [\*] set forth in [\*] Section [\*].
- (e) Except for losses or damages arising from breach of [\*] obligations or from a Party's gross negligence or willful misconduct (including, without limitation, intentional breach, non-performance or delay), neither Party shall be liable hereunder for any special, indirect, incidental, consequential or punitive damages, even if such Party shall have been advised of the possibility of such potential damages.
- (f) The Parties hereto acknowledge that the limitations of liabilities set forth in this Section 9 reflect the allocation of risk set forth in this Agreement and that the Parties would not enter into this Agreement without these limitations of liability.

## 10) Confidentiality

- (a) While this Agreement is in effect, and for a period of [\*] years after the termination of the Agreement, neither Party, nor either Party's affiliates, or any directors, shareholders, officers, employees or agents of the foregoing (collectively, the "**Affiliates**"), shall use or divulge to anyone any Confidential Information of the other Party (as hereinafter defined), except: (i) as required in the course of performing the obligations hereunder; (ii) to attorneys, accountants and other advisors; (iii) with the express written consent of the other Party; or (iv) as required by law (provided that such Party shall promptly notify the other Party of such required disclosure and shall reasonably assist such other Party to obtain a protective order limiting or restricting the required disclosure). In addition, Customer shall have the right to disclose and use WuXi AppTec's Confidential Information to the extent necessary or useful for Customer's development, commercialization or other exploitation of the Product or other results or deliverables of the Services. The term "**Confidential Information**" of a Party shall mean any information relating to such Party or its business which is (1) disclosed to the other Party (or to the other Party's Affiliates) during the negotiation of and performance of this Agreement and (2) is marked "Confidential" if provided in writing, or if delivered verbally, is reduced to writing within [\*] and marked "Confidential." In addition, all Data and Inventions (as defined in Section 19(a)) shall be deemed Customer's Confidential Information. "Confidential Information" shall not include any information which: (i) becomes public knowledge without breach by the other of this Agreement; (ii) is obtained by the other (or the other's Affiliates) from a person or business entity under circumstances permitting its disclosure to others; or (iii) may be demonstrated to have been known at the time of receipt thereof as evidenced by tangible records. If a party makes a disclosure of Confidential Information that is permitted by the terms of this Agreement, such party shall be

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responsible for ensuring that the person to whom it is disclosed maintains the confidentiality of such Confidential Information in accordance with the terms of this Agreement.

**11) Termination.**

- (a) Customer has the right to terminate this Agreement or any Work Order for any reason or no reason by delivery of written notice of such termination to WuXi AppTec effective [\*] following delivery of such notice. In addition, each Party has the right to terminate this Agreement by delivery of written notice of such termination to the other Party effective immediately upon the receipt of such notice, upon the occurrence of any of the following events:
- (i) In the event that the other Party shall be adjudicated bankrupt or shall petition for or consent to any relief under any bankruptcy, reorganization, receivership, liquidation, compromise, or any moratorium statute, whether now or hereafter in effect, or shall make an assignment for the benefit of its creditors, or shall petition for the appointment of a receiver, liquidator, trustee or custodian is appointed for all or a substantial part of its assets and is not discharged within [\*] after the date of such appointment;
- (ii) Upon the failure of the other Party to remit an undisputed and past due payment required to be remitted under this Agreement within [\*] following the receipt of a written notice of such past due payment;
- (iii) Upon any default in the performance of or breach of any agreement, covenant, obligation or undertaking of the other Party made hereunder (other than a default in payment dealt with under subsection (ii) above) that has not been remedied to the reasonable satisfaction of the terminating Party within [\*] following the terminating Party's delivery of written notice of such default or breach to the other Party; or
- (iv) Upon a failure or delay of fulfillment of all or part of this Agreement that continues for a period of [\*] and results from a "force majeure" event set forth in Section 17 below.
- (b) Upon any termination or expiration of this Agreement, WuXi AppTec shall promptly return to Customer all Equipment, remaining Starting Material, all Product and other deliverables (in whatever stage of development) and all Confidential Information of Customer.
- 12) Independent Contractor.** Both Parties are independent contractors and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency or principal and agent, and neither Party is the agent of the other, and neither Party may hold itself out as such to any other party, and neither Party has the power or authority in any way to bind the other Party contractually. Each Party shall be free to manage and control its business as it sees fit without the management, control or assistance of the other Party, except as otherwise prescribed herein.
- 13) Governing Law.** This Agreement shall be governed by and construed in accordance with the laws in the State of New York, without regard to its choice of law provisions.
- 14) Entire Agreement.** This Agreement and any attachments hereto, together with any executed Work Orders and any related quality agreement, constitute the entire understanding of the Parties with respect to the matters contained herein. In case one or more amendments, modifications or alterations of this Agreement become necessary, the Parties shall negotiate in good faith on such amendments, modifications or alterations. This Agreement may be amended, modified or altered only by an instrument in writing duly executed by both Parties.
- 15) Force Majeure.** The Parties hereto shall not be liable in any manner for the failure or delay of fulfillment of all or part of this Agreement, directly or indirectly, owing to governmental orders or

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restrictions, war, war-like conditions, revolution, riot, looting, strike, lockout, fire, flood or other external causes or circumstances beyond the Parties' control. Neither WuXi AppTec nor Customer shall be liable for any default, damages (including without limitation any direct, indirect, foreseeable, unforeseeable, consequential or punitive) or delays in shipment for any cause beyond its reasonable control.

- 16) Severability.** If any one or more of the provisions of this Agreement shall for any reason be held to be illegal or unenforceable, such invalidity or unenforceability shall not affect any other provision of this Agreement or the validity or enforceability of such provision. The unenforceable provision shall be treated as severable and the remaining provisions shall nevertheless continue in full force and effect, giving maximum effect to the intent of the Parties in entering this Agreement.
- 17) Survivability.** This Agreement shall be binding upon and enure to the benefit of the Parties hereto and their respective legal successors. The following provisions shall survive any termination or expiration of this Agreement: Sections 9, 10, 11(b), 12 through 24.
- 18) Arbitration**
- (a) In the event of any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, each party shall by written notice to the other have the right to have such dispute referred to the senior management of WuXi AppTec and Customer for attempted resolution by good faith negotiations within [\*] after such notice is received. If such senior management is unable to resolve such dispute within such [\*] period, either Party may invoke the provisions of Section 18(b). Any settlement reached by the Parties under this Section shall not be binding until reduced to writing and signed by the above-specified management of WuXi AppTec and Customer. When reduced to writing, such agreement shall supersede all other agreements, written or oral, to the extent such agreements specifically pertain to the matters so settled.
- (b) In the event of the failure to reach a resolution pursuant to Section 18(a), any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, shall be finally settled by binding arbitration. If WuXi AppTec initiates arbitration, the site of arbitration shall be [\*]. If Customer initiates arbitration, the site of arbitration shall be [\*]. All disputes shall be settled by three (3) arbitrators. Each Party shall choose one arbitrator from a panel of arbitrators who are residents of the United States, in accordance with the Commercial Arbitration Rules then in effect of the American Arbitration Association (the "**AAA Rules**"), and the two arbitrators so chosen shall choose a third arbitrator. Any such arbitration shall be conducted in the English language and shall be conducted pursuant to AAA Rules. Any arbitration award shall be final and binding and no appeal shall lie therefrom. Judgment upon the award may be entered in any court of competent jurisdiction. Other than as provided in Section 18(c) below, except for each Party's own attorney's fees and any expenses incurred in producing its own witnesses, all other administrative expenses shall be divided as directed by the arbitrators.
- (c) If either Party, notwithstanding the foregoing, should attempt either to resolve any dispute arising in connection with this Agreement in a court of law or equity or to forestall, preempt, or prevent arbitration of any such dispute by resort to the process of a court of law or equity, and such dispute is ultimately determined to be arbitral by such court of law or equity, the arbitrators shall include in their award an amount for the other Party equal to all of that other Party's costs, including legal fees, incurred in connection with such determination. Nothing in this Section 18 shall prevent a Party from seeking a remedy in a court of equity if money damages are not an adequate remedy, (such as enforcement of the confidentiality provisions of this Agreement) or in order to preserve the status quo pending an arbitration award.
- 19) Inventions and Technology Transfer.**

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

- (a) All data, information and intellectual property generated or derived by WuXi AppTec as a direct result of the Services performed by WuXi AppTec under this Agreement (collectively, the “**Data and Inventions**”) shall belong solely to Customer. WuXi AppTec hereby assigns to Customer all right, title and interest in and to the Data and Inventions. WuXi AppTec shall promptly disclose all Data and Inventions to Customer and shall reasonably assist Customer to perfect Customer’s ownership in the Data and Inventions and to apply for, secure and maintain patent and other proprietary protection of the Data and Inventions. Notwithstanding the foregoing, Customer acknowledges that WuXi AppTec possesses certain inventions, processes, know-how, trade secrets, other intellectual property and assets, including but not limited to production methods, test methods, computer technical expertise and software, which have been independently developed by WuXi AppTec (collectively, the “**WuXi AppTec Property**”). Customer and WuXi AppTec agree that any WuXi AppTec Property or improvements thereto which are used, improved, modified or developed by WuXi AppTec under or during the term of this Agreement, are the product of WuXi AppTec’s technical expertise possessed and developed by WuXi AppTec prior to or during the performance of this Agreement and are the sole and exclusive property of WuXi AppTec, except that WuXi AppTec hereby grants to Customer a world-wide, non-exclusive, royalty free, perpetual and irrevocable license (with the right to sublicense) to use such WuXi AppTec Property and improvements, modifications or developments made while performing the Services, solely to the extent such WuXi AppTec Property or improvements, modifications or developments are [\*] and/or the use of which is [\*] for Customer’s full lawful use of the deliverables provided by WuXi AppTec hereunder (including the development, manufacture, commercialization or other exploitation of the Product).
- (b) After expiration or termination of this Agreement, or in the event that WuXi AppTec files a petition of any type as to its bankruptcy, is declared bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, goes into liquidation or receivership, loses legal control of its business, ceases to carry on its business as a contract manufacturing organization, or [\*] Customer’s manufacturing needs, then at Customer’s written request, WuXi AppTec will transfer to Customer (or Customer’s designee, including its other contract manufacturers) all developments related to Product and other WuXi AppTec know-how used in or necessary for the production of Product. In connection with such technology transfer and upon reasonable notice, WuXi AppTec will permit reasonable access to the WuXi AppTec Plant during normal business hours to employees of Customer to learn about the relevant developments and know-how used to produce Product. Prior to any such technology transfer, such employees will each enter into a customary confidentiality agreement, which will be commercially reasonable and will permit such employees to disclose information learned to Customer or its designee and will restrict use of such WuXi AppTec know-how to use solely in connection with the manufacture Product (or any derivative thereof). Customer shall compensate WuXi AppTec [\*] for providing such technical assistance. For clarity, in the event that Customer requests such technology transfer to a third party contract manufacturer, access to WuXi AppTech Plant shall be provided to employees of Customer only, and such Customer employees shall have the right to disclose (subject to a customary confidentiality agreement as set forth above) WuXi AppTech know-how to such third party to facilitate the technology transfer to such third party. WuXi AppTec is obligated to transfer documents, information or know-how, including standard operating procedures, only to the extent that any of the foregoing is either WuXi AppTec Property that is licensed to Customer pursuant to Subsection 19(a) or is reasonably necessary for the production of Product.
- 20) Waiver.** No waiver of any term, provision or condition of this Agreement (whether by conduct or otherwise) in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition of this Agreement
- 21) Notices.** Any notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other Party shall be in writing and shall be deemed to have been sufficiently given for all purposes, and effective as of the date of receipt, if mailed by certified mail

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return receipt requested, postage prepaid, addressed to such other Party at its respective address as follows:

If to WuXi AppTec: WuXi AppTec, Inc.  
4751 League Island Blvd.  
Philadelphia, PA 19112  
Attn: Business Development

If to Customer: NewLink Genetics Corporation  
2503 South Loop Drive, Suite 5100  
Ames, IA 50010

- 22) **Press Releases.** Except as necessary to comply with applicable laws, the text of any press release or other communication to be published by or in the media concerning the subject matter of the Agreement shall require the prior written approval of WuXi AppTec and Customer.
- 23) **Assignment.** Neither Party shall be entitled to assign, transfer, charge or in any way make over the benefit and/or the burden of this Agreement without the prior written consent of the other Party which consent shall not be unreasonably withheld or delayed, save that either Party shall be entitled without the prior written consent of the other Party to assign or transfer this Agreement to its Affiliate or its successor-in-interest to all or substantially all of its assets to which this Agreement relates, whether in connection with a merger, acquisition, sale of asset or other similar transaction. WuXi AppTech may not subcontract or delegate any of its obligations hereunder to a third party without Customer's express prior written consent.
- 24) **No Third Party Beneficiaries.** The Parties to this Agreement do not intend that any terms hereof should be enforceable by any person who is not a party to this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

WuXi AppTec, Inc.

NewLink Genetics Corporation

By: \_\_\_\_\_ By: \_\_\_\_\_

Name: \_\_\_\_\_ Name: \_\_\_\_\_

Title: \_\_\_\_\_ Title: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_

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**Development and Process Transfer Program Leading to Commercial Manufacturing  
for algenpantucel-L HyperAcute™ Pancreas**

**Technical Transfer, Verification / Process Development, Process Validation, and cGMP  
Manufacturing  
of [\*] and [\*]**

BY AND BETWEEN:

**NewLink Genetics, Inc.  
2503 South Loop Drive  
Building 5, Suite 5100  
Ames, IA 50010  
USA**

**Vickie Hall  
Email: vhall@linkp.com  
Phone: (515) 598-2556**

AND

**WuXi AppTec, Inc.  
4751 League Island Boulevard  
Philadelphia, PA 19112  
USA**

EXPIRATION DATE:  
**December 31, 2015**

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This Work Order is by and between NewLink Genetics, Inc. ("Customer") and WuXi AppTec, Inc. ("WuXi AppTec"), and upon execution will be incorporated into the Cell Therapy Manufacturing and/or Tissue Processing Agreement between Customer and WuXi AppTec dated (the "Agreement"). Capitalized terms in this Work Order will have the same meaning as set forth in the Agreement.

WHEREAS, Customer hereby engages WuXi AppTec to provide the following services to support and provide for the GMP manufacturing and testing of [\*] and [\*]:

**PROJECT DESCRIPTION**

General Specifications	
Allogeneic Product	[*] and [*] for Algenpantucel-L
Development Phase	Commercial
Actual Start	[*]
Regulatory Arena	US, EU
Stage 1: Technology Transfer / Equipment Purchase & Qualification	
Technology Transfer and Verification of Transferred Data [*]	<ul style="list-style-type: none"> <li>Representatives from NewLink Genetics will conduct [*] training/observation at WuXi AppTec and/or WuXi personnel will observe [*] at NewLink, as necessary</li> <li>Documentation Preparation</li> <li>Verification Runs comparing WuXi and NewLink Genetics [*]</li> </ul>
Preparation of [*] Suites and Equipment Transfer (for [*])	<ul style="list-style-type: none"> <li>Preparation of [*] Suites and Equipment [*] for [*] equipment (e.g. [*])</li> <li>Receipt of [*] and [*] of [*] (Includes [*])</li> <li>Operator Training</li> <li>Establishing in [*] system for [*]</li> </ul>
[*] Process Validation [*] (for [*])	<ul style="list-style-type: none"> <li>Preparation of custom [*] batch record for both [*] and [*]</li> <li>Challenge [*] transfers, [*], and [*] process steps</li> <li>Includes [*] and [*] analysis</li> </ul>
[*] Qualification	<ul style="list-style-type: none"> <li>Preparation of custom [*] batch record for [*] using the [*] system</li> <li>Performed as [*] at [*]</li> <li>Includes [*] and [*] analysis</li> </ul>
NOTE:[*] is required if there is a change in the [*] or if alternate [*] such as the [*] technology.	

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Stage 2: Process / New Technology Development	
Process Optimization/Development	<p><u>[*] Concentration</u></p> <ul style="list-style-type: none"> <li>• Continued Evaluation of [*] as a [*] system for [*] and [*]</li> <li>• Identify [*], and [*] of [*]</li> <li>• Define [*] and determine [*]</li> <li>• Determine [*]</li> <li>• Determine [*]</li> <li>• Determine [*] and [*]</li> <li>• Define [*]. ([*] will be reviewed with NewLink Genetics for acceptance).</li> </ul> <p><u>Development of [*]</u></p> <ul style="list-style-type: none"> <li>• Evaluation of [*] and process [*] for [*] for the [*].</li> <li>• [*] and [*].</li> <li>• Assessment of risks associated with [*], and potential mitigation strategies</li> <li>• Defining a [*] for managing the [*], including a [*], suitable for [*] as part of the [*].</li> </ul>
Stage 3: Pilot / Engineering Lots	
[*]: Summary of Expected Pilot Process Steps	<ul style="list-style-type: none"> <li>• Procurement and release of [*], and [*] required for each pilot run</li> <li>• [*] Monitoring</li> <li>• [*] following [*] batch record [*] <ul style="list-style-type: none"> <li>• [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> </ul> </li> </ul> <p>Assumptions:</p> <ul style="list-style-type: none"> <li>• [*]</li> <li>• [*]</li> </ul>

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<p>[*]: Summary of Expected Pilot Process Steps</p>	<ul style="list-style-type: none"> <li>• Procurement and release of [*], and [*] required for each pilot run</li> <li>• [*] Monitoring</li> <li>• [*] following [*] batch record [*]             <ul style="list-style-type: none"> <li>• [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> </ul> </li> </ul> <p>Assumptions:</p> <ul style="list-style-type: none"> <li>• [*]</li> <li>• [*]</li> </ul>
<p><b>Stage 3: Pilot / Engineering Lots (Continued)</b></p>	
<p>[*]: Summary of Expected Engineering Run Process Steps</p>	<ul style="list-style-type: none"> <li>• Procurement and release of [*], and [*] required for each pilot run</li> <li>• [*] Monitoring</li> <li>• [*] following [*] batch record [*]             <ul style="list-style-type: none"> <li>• [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> </ul> </li> </ul> <p>Assumptions:</p> <ul style="list-style-type: none"> <li>• [*]</li> <li>• [*]</li> </ul>
<p>[*]: Summary of Expected Engineering Run Process Steps</p>	<ul style="list-style-type: none"> <li>• Procurement and release of [*], and [*] required for each pilot run</li> <li>• [*] Monitoring</li> <li>• [*] following [*] batch record [*]             <ul style="list-style-type: none"> <li>• [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*]</li> <li>• Day [*] / Day [*]</li> <li>• Day [*]</li> </ul> </li> </ul> <p>Assumptions:</p> <ul style="list-style-type: none"> <li>• [*]</li> <li>• [*]</li> </ul>

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Stage 4: Conformance Lots	
[*] lots of [*] and [*]	<ul style="list-style-type: none"> <li>WuXi AppTec will generate [*] in conjunction with NewLink Genetics.</li> <li>Procurement and release of [*], and [*] required for each run</li> <li>[*] Monitoring</li> <li>[*] following [*] batch record [*]</li> <li>Upon completion of [*] lots and [*] testing, WuXi AppTec will generate a [*] report.</li> </ul> <p>Assumptions:</p> <ul style="list-style-type: none"> <li>[*] will be identified by NewLink Genetics and WuXi AppTec for [*].</li> <li>[*] price [*] for [*] and [*] assumes [*]. If [*].</li> </ul>
Stage 5: Demonstration Lots	
[*] Lots of [*] and [*]	<ul style="list-style-type: none"> <li>Procurement and release of [*], and [*] required for each run</li> <li>[*] Monitoring</li> <li>[*] following [*] batch record [*]</li> </ul> <p>Assumption:</p> <ul style="list-style-type: none"> <li>[*].</li> </ul>

## SERVICE DESCRIPTION

### 1.0 Project Management

#### 1.1 Project Team.

The executive management-level director, project manager, Quality Assurance, and manufacturing and testing core team members will comprise the WuXi AppTec project team for the Customer Project. Staff members with the essential relevant background will be assigned to this team.

#### 1.2 Project Manager.

A Project Manager will serve as the primary link between Customer and WuXi AppTec to ensure on-going compliance with project goals. In order to ensure successful completion of the project, the Project Manager will be responsible for the following:

- 1.2.1 Fielding questions and monitoring accurate implementation of instructions.
- 1.2.2 Interfacing with the project team and all other functions (quality, raw materials testing, logistics control, etc.) to ensure that project timelines and cost objectives are met.
- 1.2.3 Scheduling resources to provide efficient and rapid transitions throughout the phases of this project.
- 1.2.4 Coordinating delivery of on-going project tracking reports and summaries in a mutually agreed upon format.
- 1.2.5 Facilitating team meetings.
- 1.2.6 Coordinating/finding solutions to project issues in a proactive and timely manner.
- 1.2.7 Implementing the project communication plan.
- 1.2.8 Ensuring invoices to Customer are appropriate for work performed.

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## 2.0 Technology Transfer

### 2.1 Product and Process Specific Assay Procedures and Data.

NewLink Genetics will provide development reports, SOPs and other related documents, and information concerning the analytical and potency methodologies specific for the project/product.

### 2.2 [\*] Production Processes and Data.

NewLink Genetics will provide the [\*] reports, SOPs, and other related documents, and information concerning the [\*], in-process and final product [\*]. [\*] concerning in-process and final product specifications should include, but not necessarily be limited to, [\*].

### 2.3 Initializing Manufacturing Facilities, [\*] Procurement, Qualification and Release for GMP Manufacture.

WuXi AppTec will adapt processing facilities and process equipment to incorporate the production of [\*] and [\*] under WuXi AppTec's processing procedures within the WuXi AppTec GMP manufacturing facility. WuXi AppTec and NewLink Genetics will review sourcing of [\*] by WuXi AppTec, lead times for equipment acquisition, shipment and set up of the specialized NewLink Genetics equipment, [\*] of equipment, and qualification of any [\*] that may be currently used in the process. [\*].

### 2.4 Document Preparation.

WuXi AppTec will generate batch records, commodity specifications, SOPs, data collection details and other documents to accommodate acceptance of NewLink Genetics assays and processes, as necessary.

### 2.5 Client Visits and Observation

NewLink Genetics has the option to have person in plant present during significant phases of the program.

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### 3.0 Process Development Studies

#### 3.1 [\*]:

WuXi AppTec will perform studies to [\*] as a [\*] system [\*]. The studies will determine [\*] specifications and process parameters.

#### 3.2 Process Optimization / [\*]

WuXi AppTec will perform small-scale studies of [\*] to enable application of a [\*] for the manufacturing process. Focus will be upon the [\*] which will allow for [\*]. Risks associated with [\*] will be assessed, and potential mitigation strategies identified. In addition, WuXi AppTec will propose a process for managing the [\*], including a [\*], suitable for [\*] as part of the [\*].

#### 3.3 Process Development Report

A summary report of the process development activities will be provided to both project teams for review. After review and acceptance of the report a plan for pilot production or additional process development activities will be developed before moving forward.

#### 3.5 Vendor Qualification

WuXi AppTec will conduct vendor qualification and audits of suppliers according to current quality policies, procedures and according to the Quality Agreement executed established with NewLink Genetics. WuXi AppTec will conduct material qualification analysis of appropriate lots of [\*], supplies and components.

### 4.0 [\*] Manufacture / Characterization

#### 4.1 Batch Record and Documentation Preparation

WuXi AppTec will create master batch records by combining information from NewLink Genetics, as well as from any process development and verification/qualification run data with manufacturing standard operating procedures and process flows. WuXi AppTec and NewLink Genetics will determine and define any special conditions regarding [\*]; develop acceptance criteria for [\*] and [\*]. WuXi AppTec will provide material specifications, test methods, data collection details and other documents to accommodate acceptance of the process into the production area.

#### 4.2 Facility / Production Suite Preparation

WuXi AppTec will commission [\*] production suites for GMP operations which will be dedicated to the [\*] and [\*] production effort. [\*] are commissioned, three for [\*] and one for [\*]. New equipment will be appropriately configured according to WuXi AppTec's procedures, installed and qualified and incorporated into the [\*] monitoring system. Facility and suite modifications will be performed as agreed upon by both WuXi and NewLink Genetics and completed in advance of GMP manufacturing activities.

#### 4.3 [\*] Pilot Manufacturing Runs

WuXi AppTec will produce final product vials following [\*] for both [\*] and [\*]. [\*]. A Certificate of Testing will be generated upon completion of [\*].

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4.4 [\*] Engineering Runs

WuXi AppTec will produce final product vials following [\*] batch records for both [\*] and [\*]. [\*]. A Certificate of Testing will be generated upon completion of [\*]. Material from these runs may be utilized to [\*].

4.5 Media Challenges

WuXi AppTec will perform [\*] validation runs using [\*] to challenge the full scale process in [\*] transfers, [\*] and sampling. [\*]. The fill process will be challenged using [\*].

4.6 Conformance Lots

WuXi AppTec will prepare QA reviewed process validation protocols. NewLink Genetics will review these protocols. WuXi AppTec will perform [\*] lots under cGMP for both [\*] and [\*]. Each product lot will be required to meet the criteria detailed in the validation document. A Certificate of Analysis will be generated upon completion of [\*].

4.7 Vialing, Labeling, of [\*]

WuXi AppTec will vial and label the formulated [\*]. Labeling will be agreed upon by both WuXi and NewLink Genetics.

4.8 Lot-Release Testing

Characterization and biosafety tests for the release of each cell lot will be conducted [\*] based on U.S. FDA and ICH guidelines. (See Testing Section)

4.9 [\*] Storage

WuXi AppTec will store the [\*] under appropriate product label storage conditions and in a secure area to insure they comply with the quality specifications and attributes.

4.10 Testing and Characterization

WuXi AppTec will test the product lots under current FDA and ICH guidelines. See Recommended Testing Programs Section.

4.11 Validation Summary Reports

WuXi AppTec will generate QA reviewed summary reports for process validation post successful completion of conformance campaign.

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## 5.0 Analytical Method Transfer

- 5.1 The characterization and safety tests are outlined in the Testing Section. All of the routine assays for the assessment of the [\*] are available or can be developed in the Process Development and Testing departments. WuXi AppTec has well-established testing programs with batch records spanning technical areas such as virus detection, analytical analysis, DNA analysis and characterization; residual analysis, potency assays, cell viability, flow cytometry, and other standard cell biology methods. Batch records are in place for these assays and a custom assay program is available for rapid assay transfer, development, qualification, and document preparation.
- 5.2 For assay transfer, initial work will involve discussion with NewLink Genetics and transfer of any existing technology as documents or expertise. NewLink Genetics personnel may assist and visit WuXi AppTec to share technical details. Based on the assay-specific technology transfer documents, protocols will be written by WuXi AppTec personnel following document-specific SOPs. Documents will be circulated for review and approval, with final approval by the Production Manager or Study Director and the Quality Assurance department. If a batch record is already in place for a given assay, then WuXi AppTec and NewLink Genetics may jointly decide that the assay may be verified for use with NewLink Genetics' specific product or process intermediate. This will be done by assaying that material (using the existing batch record) to determine any interference or other influence the material may have on the assay.
- 5.3 Compendia methods, by definition will be run cGMP. Other analytical or QC methods required to be performed cGMP need to be validated to the level appropriate for the stage of product development. In this instance, acceptance criteria for the assay would be established during assay development. These will be included in a validation protocol that will analyze required components of assay validation, based on ICH or USP guidelines and following WuXi AppTec's internal validation program. [\*].

## 6.0 Chemistry, Manufacturing and Controls Documentation

### 6.1 CMC Section Documentation

WuXi AppTec will provide the necessary documentation and data required to assist NewLink Genetics in developing the CMC section of a regulatory submission to FDA and/or other regulatory authority equivalents.

- 6.1.1 Description of the Manufacturer's organization, including facility and the general activities and types of products supported in the facility.
- 6.1.2 Data from the testing of NEWLINK GENETICS [\*].
- 6.1.3 A description and flow chart of the process steps used in the production of the [\*].
- 6.1.4 Tables listing the types, grades and sources of the [\*].

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## Price Summary [\*]

- [\*]

[\*] Production Pricing Estimate: Newlink [\*]

Stage 1: Technology Transfer / Initialization and Qualification – Existing Facility

[\*]

Stage 2: Process / New Technology Development

[\*]

Stage 3: Pilot / Engineering Lots

[\*]

Stage 4: Conformance Lots

[\*]

Stage 5: Demonstration Lots

[\*]

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[\*]

- [\*]

[\*] Production Pricing Estimate: NewLink [\*]

Stage 1: Technology Transfer / Initialization & Qualification – Existing Facility

[\*]

Stage 2: Process / New Technology Development

[\*]

Stage 3: Pilot / Engineering Lots

[\*]

Stage 4: Conformance Lots

[\*]

Stage 5: Demonstration Lots

[\*]

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LOT RELEASE TESTING OF [\*]

[\*]

[\*]

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## ESTIMATED TIMELINE

The timeline will be a working timeline with the team throughout the duration of the program. The current working timeline is attached as Appendix 1.

## PAYMENT TERMS

1. Invoicing will be as follows:
  - [\*] for [\*] (excluding the following) upon [\*], and [\*] at [\*].
    - a. [\*] will be invoiced [\*] upon [\*]
    - b. [\*] will be invoiced monthly
    - c. [\*] will be invoiced [\*] upon [\*] and [\*] at [\*].
  - [\*] charged at [\*] will be invoiced at least monthly for [\*] at the time of [\*]. [\*] not charged at [\*] will be invoiced [\*] upon [\*] and [\*] at [\*]. [\*].
  - [\*] of [\*] and [\*] will be invoiced [\*] upon [\*] and [\*] at [\*].
  - [\*] and [\*] will be invoiced [\*] upon [\*] and [\*] upon [\*]. The remaining [\*] will be invoiced upon [\*] of the [\*] or [\*] after [\*] whichever is sooner.
  - [\*] of [\*] and [\*] will be invoiced upon [\*].
  - [\*] will be invoiced [\*] upon [\*] and [\*] upon [\*].
  - [\*] will be billed at [\*] of the [\*] at the [\*].

Terms are [\*]. Invoices are “billed and payable” in [\*].

2. All [\*], and all other [\*] and [\*] purchased by WuXi AppTec ([\*] will be asked to [\*] and [\*] in a [\*] prior to purchase) will be invoiced upon [\*] at [\*]. [\*], and all other [\*] and [\*] will be invoiced [\*]. [\*] and other [\*] will be [\*] upon [\*] and [\*]. Terms are [\*]. Invoices are “billed and payable” in [\*].

## MODIFICATION

This Work Order may be supplemented, amended or modified only by the mutual agreement of the parties. No supplement, modification or amendment of this Work Order shall be binding unless it is in writing and signed by both parties. Any material change to the Services will require an amendment in writing signed by authorized representatives of both parties in accordance with the Master Agreement.

All other terms and conditions of the Agreement will apply to this Work Order.

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

WORK ORDER AGREED TO AND ACCEPTED BY:

**NewLink Genetics, Inc.**

**WUXI APPTEC, INC.**

By \_\_\_\_\_ By \_\_\_\_\_  
Duly authorized Duly authorized

Print Name \_\_\_\_\_ Print Name \_\_\_\_\_

Title \_\_\_\_\_ Title \_\_\_\_\_

Date \_\_\_\_\_ Date \_\_\_\_\_

**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**

**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, 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.

##### (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, 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.

**(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:

**(v) 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.

**(vi) 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.

**(vii) 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.

**(viii) 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.

**(ix) 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.

**(x) 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.

(bb) "**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.

(cc) "**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).

**(dd)** “*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.

**(ee)** “*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.

**(ff)** “*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.

**(gg)** “*Plan*” means this NewLink Genetics Corporation 2010 Non-Employee Directors’ Stock Award Plan.

**(hh)** “*Restricted Stock Award*” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(a).

**(ii)** “*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.

**(jj)** “*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).

**(kk)** “*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.

**(ll)** “*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.

**(mm)** “*Securities Act*” means the Securities Act of 1933, as amended.

**(nn)** “*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.

**(oo)** “*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.

**(pp)** “*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.

**(qq)** “*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.

**(rr)** “*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.

**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 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.

**NEWLINK GENETICS CORPORATION  
RESTRICTED STOCK UNIT GRANT NOTICE  
(2010 NON-EMPLOYEE DIRECTOR STOCK AWARD PLAN, AS AMENDED)**

NewLink Genetics Corporation (the “*Company*”), pursuant to Section 7(b) of the Company’s 2010 Non-Employee Director Stock Award Plan, as amended (the “*Plan*”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“*Restricted Stock Units*”) set forth below (the “*Award*”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “*Restricted Stock Unit Grant Notice*”) and in the Plan and the Restricted Stock Unit Award Agreement (the “*Award Agreement*”), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant: \_\_\_  
 ID: \_\_\_  
 Date of Grant: \_\_\_  
 Grant Number: \_\_\_  
 Vesting Commencement Date: \_\_\_  
 Number of Restricted Stock Units/Shares: \_\_\_

**Vesting Schedule:** The shares subject to the Award shall vest as follows: 100% of the shares will 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, subject to the Participant’s Continuous Service on each applicable vesting date.

**Issuance Schedule:** Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) the written employment agreement or offer letter agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the

Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

Other Agreements: \_\_\_\_\_

**NEWLINK GENETICS CORPORATION PARTICIPANT**

By: \_\_ \_\_  
Signature Signature

Title: \_\_ Date: \_\_

Date: \_\_

**ATTACHMENTS:** Award Agreement and 2010 Non-Employee Director Stock Award Plan, as amended

**NEWLINK GENETICS CORPORATION**  
**2009 EQUITY INCENTIVE 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 6(b) of the Company’s 2009 Equity Incentive 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.

**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.

**NEWLINK GENETICS CORPORATION  
RESTRICTED STOCK UNIT GRANT NOTICE  
(2009 EQUITY INCENTIVE PLAN, AS AMENDED)  
[FOUR YEAR ANNUAL VESTING]**

NewLink Genetics Corporation (the “*Company*”), pursuant to Section 6(b) of the Company’s 2009 Equity Incentive Plan, as amended (the “*Plan*”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“*Restricted Stock Units*”) set forth below (the “*Award*”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “*Restricted Stock Unit Grant Notice*”) and in the Plan and the Restricted Stock Unit Award Agreement (the “*Award Agreement*”), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant: \_\_\_  
 ID: \_\_\_  
 Date of Grant: \_\_\_  
 Grant Number: \_\_\_  
 Vesting Commencement Date: \_\_\_  
 Number of Restricted Stock Units/Shares: \_\_\_

**Vesting Schedule:** The shares subject to the Award shall vest as follows: 25% of the shares will vest on each of the first, second, third and fourth annual anniversaries of the Vesting Commencement Date, subject to the Participant’s Continuous Service on each applicable vesting date.

**Issuance Schedule:** Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) the written employment agreement or offer letter agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

Other Agreements: \_\_\_\_\_

**NEWLINK GENETICS CORPORATION PARTICIPANT**

By: \_\_ \_\_                      Signature    Signature

Title: \_\_    Date: \_\_

Date: \_\_

**ATTACHMENTS:** Award Agreement and 2009 Equity Incentive Plan, as amended

**NEWLINK GENETICS CORPORATION  
RESTRICTED STOCK UNIT GRANT NOTICE  
(2009 EQUITY INCENTIVE PLAN, AS AMENDED)  
[IMMEDIATELY VESTED]**

NewLink Genetics Corporation (the “*Company*”), pursuant to Section 6(b) of the Company’s 2009 Equity Incentive Plan, as amended (the “*Plan*”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“*Restricted Stock Units*”) set forth below (the “*Award*”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “*Restricted Stock Unit Grant Notice*”) and in the Plan and the Restricted Stock Unit Award Agreement (the “*Award Agreement*”), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant: \_\_\_  
ID: \_\_\_  
Date of Grant: \_\_\_  
Grant Number: \_\_\_  
Number of Restricted Stock Units/Shares: \_\_\_

**Vesting Schedule:** The shares subject to the Award shall be fully vested upon issuance.

**Issuance Schedule:** Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) the written employment agreement or offer letter agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

Other Agreements: \_\_\_\_\_

**NEWLINK GENETICS CORPORATION PARTICIPANT**

By: \_\_ \_\_  
Signature Signature

Title: \_\_ Date: \_\_

Date: \_\_

**ATTACHMENTS:** Award Agreement and 2009 Equity Incentive Plan, as amended

2.

## 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 5, 2014

By:  /s/ Charles J. Link, Jr.

Charles J. Link, Jr.

Chief Executive Officer

(Principal Executive Officer)

## CERTIFICATION

I, Gordon H. 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 5, 2014

By: /s/ Gordon H. Link, Jr.

Gordon H. Link, Jr.

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 Gordon H. Link, Jr., Chief Financial Officer 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, 2014, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 5, 2014

By: /s/ Charles J. Link, Jr.

Charles J. Link, Jr.

Chief Executive Officer

(Principal Executive Officer)

By: /s/ Gordon H. Link, Jr.

Gordon H. Link, Jr.

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.