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 September 30, 2018.
o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the transition period from to .
Commission File Number
001-35342

NEWLINK GENETICS CORPORATION

(Exact name of Registrant as specified in Its Charter)

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

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

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

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

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

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

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

As of October 30, 2018, there were 37,224,606 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 data)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 122,061	$ 158,708
Prepaid expenses and other current assets	4,920	6,226
Income tax receivable	7,398	356
Other receivables	700	10,176
Total current assets	135,079	175,466
Property and equipment, net	4,096	5,091
Income tax receivable	140	140
Total non-current assets	$ 4,236	5,231
Total assets	$ 139,315	$ 180,697
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,238	$ 9,256
Accrued expenses	8,736	12,467
Current portion of unearned revenue	—	56
Current portion of deferred rent	84	92
Current portion of notes payable and obligations under capital leases	74	160
Total current liabilities	10,132	22,031
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	59	111
Deferred rent	929	998
Total long-term liabilities	6,988	7,109
Total liabilities	17,120	29,140
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at September 30, 2018 and December 31, 2017; issued and outstanding shares — 0 at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at September 30, 2018 and December 31, 2017; issued 37,305,626 and 37,168,122 at September 30, 2018 and December 31, 2017, respectively, and outstanding 37,216,892 and 37,109,556 at September 30, 2018 and December 31, 2017, respectively	373	372
Additional paid-in capital	403,674	389,786
Treasury stock, at cost: 88,734 and 58,566 shares at September 30, 2018 and December 31, 2017, respectively	(1,409)	(1,142)
Accumulated deficit	(280,443)	(237,459)
Total stockholders' equity	122,195	151,557
Total liabilities and stockholders' equity	$ 139,315	$ 180,697

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Grant revenue	$ —	$ 5,379	$ 11,268	$ 18,279
Licensing and collaboration revenue	120	103	1,004	334
Total operating revenues	120	5,482	12,272	18,613
Operating expenses:				
Research and development	7,570	18,480	39,972	52,405
General and administrative	7,588	7,907	23,792	25,038
Total operating expenses	15,158	26,387	63,764	77,443
Loss from operations	(15,038)	(20,905)	(51,492)	(58,830)
Other income and expense:				
Miscellaneous (expense) income	(18)	12	16	(101)
Interest income	664	151	1,510	353
Interest expense	(2)	(3)	(51)	(116)
Other income, net	644	160	1,475	136
Net loss before taxes	(14,394)	(20,745)	(50,017)	(58,694)
Income tax benefit	6,991	119	6,991	429
Net loss	$ (7,403)	$ (20,626)	$ (43,026)	$ (58,265)
Basic and diluted loss per share	$ (0.20)	$ (0.69)	$ (1.16)	$ (1.98)
Basic and diluted average shares outstanding	37,214,363	29,939,823	37,178,542	29,462,226

See accompanying notes to condensed consolidated financial statements.

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

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	37,109,556	$ 372	$ 389,786	$ (1,142)	$ (237,459)	$ 151,557
Share-based compensation	—	—	13,620	—	—	13,620
Exercise of stock options and restricted stock vested	105,393	1	138	—	—	139
Sales of shares under stock purchase plan	32,111	—	130	—	—	130
Repurchase of common stock	(30,168)	—	—	(267)	—	(267)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(43,026)	(43,026)
Balance at September 30, 2018	37,216,892	$ 373	$ 403,674	$ (1,409)	$ (280,443)	$ 122,195

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	**2017**
Cash Flows From Operating Activities		
Net loss	$ (43,026)	$ (58,265)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	13,620	14,938
Depreciation and amortization	901	1,064
(Gain) Loss on sale of fixed assets	(16)	102
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	842	3,220
Other receivables	9,982	13,856
Accounts payable and accrued expenses	(11,749)	(11,500)
Income taxes receivable	(7,042)	5,861
Unearned revenue	(56)	(279)
Deferred rent	(78)	(67)
Net cash used in operating activities	(36,622)	(31,070)
Cash Flows From Investing Activities		
Purchase of equipment	(7)	(43)
Proceeds on sale of equipment	118	185
Net cash provided by investing activities	111	142
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	269	20,585
Repurchase of common stock	(267)	(260)
Payments under capital lease obligations and principal payments on notes payable	(138)	(185)
Net cash (used in) provided by financing activities	(136)	20,140
Net decrease in cash and cash equivalents	(36,647)	(10,788)
Cash and cash equivalents at beginning of period	158,708	131,490
Cash and cash equivalents at end of period	$ 122,061	$ 120,702
Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 6	$ 11
Cash refunds received for taxes, net	$ 4	$ (6,261)

See accompanying notes to condensed consolidated financial statements.

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

1. Description of Business

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed for the purpose of developing treatments for patients with cancer and other diseases. NewLink initiated operations in April 2000.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs.

The accompanying condensed consolidated financial statements as of September 30, 2018 and for the three and nine months 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 in 2013, and raised an additional $58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

During 2017, the Company sold 1,940,656 shares of its common stock under an ATM offering, with aggregate net proceeds of $19.3 million after commissions of $398,000 paid to Cantor Fitzgerald & Co. (Cantor) as the placement agent, and other costs of $163,000. In October 2017, the Company sold 5,750,000 of its shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million. On March 12, 2018, the Company entered into a new Sales Agreement with Cantor under which the Company may sell up to $60.0 million of its common stock in one or more placements at prevailing market prices in an ATM offering (the 2018 ATM Offering). As of September 30, 2018, no shares have been sold under the 2018 ATM Offering.

The Company's cash and cash equivalents as of September 30, 2018 are expected to be adequate to satisfy the Company's liquidity requirements into the second half of 2021. If available liquidity becomes insufficient to meet the Company’s operating obligations as they come due, the Company's plans include selling additional shares of common stock, alternative funding arrangements and/or reducing expenditures as necessary to meet the Company’s cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company’s ability to continue as a going concern.

2. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), and, in management’s opinion, reflect all adjustments necessary to present fairly the Company’s interim condensed financial information.

Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2017, included in the Company’s Annual Report on Form 10-K. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed 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 condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed 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.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable and capital lease obligations was $133,000 and $271,000 as of September 30, 2018 and December 31, 2017, respectively, which approximate fair value using Level 2 inputs (computed in accordance with ASC 820). The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit and money market funds.

Property and equipment

Property and equipment are capitalized as the Company believes they have alternative future uses and are stated at cost, less accumulated depreciation of $7.1 million and $6.6 million as of September 30, 2018 and December 31, 2017, respectively. Equipment under capital leases is stated at the present value of minimum lease payments. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Recently Issued Accounting Pronouncements not yet adopted

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, Leases, to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheet a right of use asset and related lease liability for all leases with terms greater than twelve months. The ASU also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company does not currently have any material leases and therefore does not anticipate adoption to have a material impact on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09 (Topic 606), Revenue from Contracts with Customers. Topic 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition" (Topic 605), and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 as of January 1, 2018 and as a result changed its accounting policy for revenue recognition, as discussed in Note 4.

4. Revenues

Adoption of ASC Topic 606, "Revenue from Contracts with Customers"

On January 1, 2018, we adopted Topic 606 using the modified retrospective method by recognizing the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of equity as of January 1, 2018. Therefore results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting policy under Topic 605. The change in accounting policy from Topic 605 to Topic 606 impacted how the Company recognizes revenue from government grants, and did not impact license and collaboration revenues due to the nature of those services in the period leading up to and after the adoption of Topic 606.

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

The Company recorded an immaterial net reduction to the opening accumulated deficit within equity as of January 1, 2018 due to the cumulative impact of adopting Topic 606 with respect to grants from government entities which were not completed as of the date of adoption. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Condensed Consolidated Balance Sheet as of January 1, 2018 (in thousands):

	As Reported December 31, 2017	Adjustments	Adjusted January 1, 2018
Balance Sheet			
Assets:			
Prepaid expenses and other current assets	$ 6,226	$ (464)	$ 5,762
Other receivables	$ 10,176	$ 506	$ 10,682
Total assets	$ 180,697	$ 42	$ 180,739
Equity:			
Accumulated deficit	$ (237,459)	$ 42	$ (237,417)
Total liabilities and stockholders' equity	$ 180,697	$ 42	$ 180,739

The impact of adoption on the Company's Condensed Consolidated Statement of Operating Loss for the three and nine months ended September 30, 2018 was as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	As Reported	Adjustments	Balance without Adoption of Topic 606	As Reported	Adjustments	Balance without Adoption of Topic 606
Statement of Operating Loss						
Grant Revenues	$ —	$ —	$ —	$ 11,268	$ 346	$ 11,614
Licensing and collaboration revenue	$ 120	$ 18	$ 138	$ 1,004	$ 164	$ 1,168
Research and Development	$ 7,570	$ 18	$ 7,588	$ 39,972	$ 468	$ 40,440
Net Loss	$ (7,403)	$ —	$ (7,403)	$ (43,026)	$ 42	$ (42,984)

The impact of adoption on the Company's Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2018 was as follows (in thousands):

	As Reported	Adjustments	Balance without Adoption of Topic 606
Statement of Cash Flows			
Net Loss	$ (43,026)	$ 42	$ (42,984)
Changes in operating assets and liabilities:			
Other receivables	$ 9,982	$ (492)	$ 9,490
Accounts payable and accrued expenses	$ (11,749)	$ 450	$ (11,299)
Net cash used in operating activities	$ (36,622)	$ —	$ (36,622)

Revenue Recognition

Revenues are recognized under Topic 606 when control of the promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company receives payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services, or HHS. These agreements provide the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized over time and measured using the input method. The Company uses labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. This is the most faithful depiction of the transfer of goods and services to the government entities due to the government entities' control over the research and development activities. Under this method, the Company recognizes revenue generally in the period during which the related costs are incurred, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

The Company had $320,000 and $9.3 million of receivables relating to the government contracts recorded in other receivables and zero and $465,000 of unbilled expenses relating to the government contracts recorded in prepaid expenses and other current assets on the balance sheet as of September 30, 2018 and December 31, 2017, respectively. The Company had $81,000 and $1.8 million of accrued expenses for subcontractor fees incurred under the government contracts as of September 30, 2018 and December 31, 2017, respectively.

5. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into an exclusive worldwide collaboration and license agreement with Genentech, or the Genentech Agreement, for the development and commercialization of NLG919, one of the Company's clinical stage IDO pathway inhibitors and for the discovery of next generation IDO/TDO compounds to be developed and commercialized under this agreement. Under the terms of the Genentech Agreement, the Company received a nonrefundable upfront cash payment of $150.0 million from Genentech in 2014. On June 6, 2017, the Company received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919. As part of the partial termination, worldwide rights to NLG919 reverted to us, and Genentech granted to us an exclusive, royalty-bearing license under certain Genentech intellectual property to develop and commercialize NLG919. If NLG919 is commercialized, we will be obligated to pay to Genentech royalties as a low single-digit percentage of net sales of NLG919.

Additionally, on May 9, 2018 the Company received formal notice that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement will terminate in its entirety no later than November 6, 2018.

For the three and nine months ended September 30, 2018, the Company recognized license and collaboration revenue under the Genentech Agreement of zero and $56,000, respectively, for providing an alliance manager. For the three and nine months ended September 30, 2017, the Company recognized license and collaboration revenue under the Genentech Agreement of $56,000 and $279,000, respectively, for providing an alliance manager. All of the deliverables identified within the collaboration and license agreement were completed in their entirety and all of the $150.0 million upfront payment was recognized as of March 31, 2018.

Merck Sharp & Dohme Corp.

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

The Merck Agreement was amended on December 5, 2017 in connection with our entry into an amended and restated PHAC license on December 5, 2017. The amended Merck Agreement absolves our subsidiary, BioProtection Systems Corporation, or BPS, from any future obligation to negotiate or amend the terms of the PHAC license, converts the scope of Merck's sublicense under PHAC's intellectual property rights to be non-exclusive in the Ebola Sudan field of use, and requires Merck to reimburse us in certain circumstances where we may be obligated to pay royalties to PHAC as a result of Merck's product sales but Merck would not otherwise be obligated to pay a royalty to us. On April 26, 2018 the Company entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced the Company as the prime contractor on all such grants. As a result grant revenues for the three and nine months ended September 30, 2018 have decreased as compared to the three and nine months ended September 30, 2017 and the Company does not expect to recognize additional revenue from government contracts for the development of the rVSVΔG-ZEBOV GP vaccine product candidate subsequent to September 30, 2018.

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. For the three and nine months ended September 30, 2018, the Company recognized license and collaboration revenues under the Merck Agreement of $120,000 and $949,000, respectively, for the reimbursement of costs not covered under government contracts. For the three and nine months ended September 30, 2017, the company recognized license and collaboration revenue under the Merck Agreement of $48,000 and $55,000, respectively, for the reimbursement of costs not covered under government contracts.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan, or the 2000 Plan, and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or the 2009 Plan. Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, the Company may grant the following types of common stock awards:

- Incentive Stock Options
- Nonstatutory Stock Options
- Restricted Stock Awards
- Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of September 30, 2018, there were 11,722,602 shares of common stock authorized for the 2009 Plan and 1,489,402 shares remained available for issuance.

The following table summarizes the authorized increases of common stock under the 2009 Plan:

Date Authorized	Authorized Shares Added
May 15, 2010	1,238,095
January 7, 2011	714,286
January 1, 2013	838,375
January 1, 2014	1,066,340
January 1, 2015	1,119,255
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382

The increases in the authorized shares of common stock under the 2009 Plan in 2010 and 2011 were approved by the Company's stockholders. The increases in the authorized shares of common stock under the 2009 Plan in 2013 through 2018 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2013 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

2010 Non-Employee Directors' Stock Award Plan

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan, or the Directors' Plan, which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of September 30, 2018, no shares remained available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company's 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of September 30, 2018, 69,885 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended September 30, 2018 and 2017 was $4.6 million and $4.4 million, respectively. Share-based compensation expense for the nine months ended September 30, 2018 and 2017 was $13.6 million and $14.9 million, respectively. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of September 30, 2018, the total compensation cost related to nonvested option awards not yet recognized was $11.8 million and the weighted-average period over which it is expected to be recognized is 2.1 years.

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions, for the nine months ended September 30, 2018:

	Number of options		Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,202,221	$	13.72	5.3
Options granted	1,632,523		6.92	
Options exercised	(32,946)		4.24	
Options forfeited	(317,359)		13.59	
Options expired	(118,097)		21.96	
Outstanding at end of period	8,371,005	$	12.32	5.1
Options exercisable at end of period	6,264,767	$	13.03	3.8

The Company estimates the fair value of each stock option grant on the date of grant using a Black-Scholes option pricing model. For stock option grants issued with a market condition, the Company used a Monte Carlo simulation valuation model to determine the grant date fair value.

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the nine months ended September 30, 2018:

Risk-free interest rate	2.6% to 2.9%
Expected dividend yield	—%
Expected volatility	76.2% to 79.2%
Expected term (in years)	4.0 to 7.9
Weighted-average grant-date fair value per share	$4.90

The intrinsic value of options exercised during the nine months ended September 30, 2018 was $77,788. The fair value of awards vested during the nine months ended September 30, 2018 was $10.2 million.

During the nine months ended September 30, 2018, the Company’s Board of Directors approved and granted 466,750 shares of equity awards to certain executives with either market or performance conditions. The equity awards had a weighted-average grant date fair value per share of $5.33. The equity awards will vest upon the achievement of certain performance conditions. Certain performance conditions relating to the equity awards granted in 2018 and 2017 were met during the nine months ended September 30, 2018 and 213,725 shares were vested.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for as 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 classified as equity within the consolidated balance sheets. The fair value of each restricted stock grant is estimated on the date of grant using the closing price of the Company's common stock on the NASDAQ Stock Market on the date of grant.

A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at September 30, 2018 and changes during the nine months ended September 30, 2018 are as follows:

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

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	168,221	$ 35.82
Granted	—	—
Vested	(72,447)	35.40
Forfeited/cancelled	(6,721)	40.99
Unvested at end of period	89,053	$ 35.76

As of September 30, 2018, the total remaining unrecognized compensation cost related to restricted stock was approximately $1.6 million and is expected to be recognized over a weighted-average period of 1.0 years.

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

7. Income Taxes

For the three and nine months ended September 30, 2018, the Company recorded a $7.0 million income tax benefit. The income tax benefit for the three and nine months ended September 30, 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due a refund received as a result of amendments filed to change the allocation of income for certain states for the years ending December 31, 2014 and 2015. We received the full refund subsequent to September 30, 2018. For the nine months ended September 30, 2017, the Company recorded an income tax benefit of $429,000. For the three months ended September 30, 2017, the Company recorded $119,000. Additionally, the Company has a noncurrent income tax receivable as of September 30, 2018 for $140,000 which was recorded as an income tax benefit in 2017 and is for the receipt of AMT Credit carryovers. The Tax Cuts and Jobs Act of 2017, or the Tax Act, provides that the AMT credit carryovers are partially refundable beginning in 2018 as an offset to a tax liability. The Company expects the amount to be fully refunded by 2021.

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 September 30, 2018 and December 31, 2017, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of September 30, 2018 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

8. Net Loss per Common Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Loss attributable to common stockholders	$ (7,403)	$ (20,626)	$ (43,026)	$ (58,265)
Basic and diluted weighted-average shares outstanding	37,214,363	29,939,823	37,178,542	29,462,226
Basic and diluted loss per share	$ (0.20)	$ (0.69)	$ (1.16)	$ (1.98)

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of September 30, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,371,005 and 89,053, respectively. As of September 30, 2017, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,314,006 and 181,336, respectively.

9. Restructuring Charges

The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. Employee severance costs are accrued when the restructuring actions are probable and estimable. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period. The Company also records costs incurred with contract terminations associated with restructuring activities.

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve resources to further advance its clinical development programs. Restructuring charges of $1.3 million were recorded during the three and nine months ended September 30, 2018 of which $800,000 is included within general and administrative expenses and $500,000 is included within the research and development expenses in the condensed consolidated statement of operations.

The Company undertook an organizational realignment in July 2017 to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. The Company recorded total restructuring charges of $1.7 million during the nine months ended September 30, 2017 of which $1.1 million is included within general and administrative expenses and $600,000 is included within the research and development expenses in the condensed consolidated statement of operations.

The following table shows the amount accrued for restructuring activities which is recorded within Accrued Expenses in the condensed consolidated balance sheet (in thousands):

	Employee Severance Cost	Total
Balance as of December 31, 2017	207	207
Expensed	1,323	1,323
Cash Payments	511	511
Balance as of September 30, 2018	1,019	1,019

10. Commitments and Contingencies

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

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company’s Chief Executive Officer Charles J. Link, Jr., and the Company’s Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company’s investors. In particular, the lead plaintiffs allege that the Defendants made material

misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs did not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs did not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. The lead plaintiffs filed an opposition to the motion to dismiss the second amended complaint on September 14, 2018. The Defendants filed a reply in support of the motion to dismiss the second amended complaint on October 9, 2018. Oral argument was held on October 19, 2018, after which the Court reserved decision. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action will be provided with any discovery that is provided in the Securities Action, and given an opportunity to participate in any mediation or settlement efforts in the Securities Action. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

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 ongoing and planned preclinical studies and clinical trials; the timing of the release of the results of data from ongoing preclinical studies and clinical trials; 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 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; plans to develop, commercialize, market and manufacture our product candidates; 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, 2017. 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

NewLink Genetics Corporation (the "Company", "NewLink", "we", "our" or "us") is a clinical-stage immuno-oncology company focused on developing novel immunotherapeutic products for the treatment of patients with cancer. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These lead product candidates, indoximod and NLG802 (a prodrug of indoximod), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system's tolerance to cancer.

Based on early clinical data from our Phase 1b clinical trials, our indoximod clinical program is focused on front-line acute myeloid leukemia (AML) and malignant pediatric brain tumors. These targeted indications are those with great unmet need where indoximod has produced encouraging early data. The Company plans to provide data updates at medical conferences in fourth quarter of 2018 for AML and in the first half of 2019 for malignant pediatric brain tumors. We also have a Phase 1 clinical trial for NLG802, the prodrug of indoximod, and we plan to present data in the fourth quarter of 2018 relating to this trial.

IDO Pathway Inhibitors

In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables cancer to avoid immune response. IDO is overexpressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, thereby promoting peripheral tolerance to tumor associated antigens, or TAAs. When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

The IDO pathway refers to a series of reactions initiated by the IDO enzyme that result in the reduction of the amino acid tryptophan in the local tumor environment. We believe the local presence of tryptophan in adequate concentrations promotes antitumor T-cells, and the local reduction of tryptophan combined with the presence of the break-down product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical data has suggested that IDO pathway

inhibitors may also enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation when used as a combination therapy for patients with cancer.

We have a clinical development program focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates in clinical development include indoximod and NLG802. Our product candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. Indoximod targets the IDO pathway through different mechanisms of action from enzymatic IDO inhibitors and therefore could represent a differentiated clinical and commercial opportunity. We believe indoximod acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the up regulation of mTOR, acts directly on T-cells, and modulates AhR-mediated effects.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are orally bioavailable and we believe they offer the potential to be synergistic with other therapies such as radiation, chemotherapy, vaccination and immunotherapies involving other checkpoint inhibitors such as anti-PD-1, anti-PD-L1 or anti-CLTA4. Clinical data suggests an increase in activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, has been studied in more than 800 patients to date and has been generally well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents and a cancer vaccine. Indoximod has a differentiated mechanism of action (MOA) which may demonstrate clinical benefit for patients compared to direct enzymatic inhibitors. Indoximod is currently in clinical development in combination with other cancer therapeutics for patients with AML and pediatric brain tumors.

We have finalized the dose for the salt formulation of indoximod for adult patients. Data from recent clinical trials suggest that the maximum plasma concentration levels and half-life observed after oral dosing of the new salt formulation of indoximod are modestly higher than those observed with the free base formulation.

A U.S. patent covering salt and prodrug formulations of indoximod was issued to us on August 15, 2017 providing exclusivity until at least 2036. We are currently pursuing international patent coverage for these formulations.

NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above the levels currently achievable by direct oral administration. We filed an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, in the first quarter of 2017 and the first patient was dosed with NLG802 in a Phase 1 clinical trial in July 2017. The purpose of this Phase 1 trial is to assess preliminary safety and to determine the recommended dose for subsequent Phase 2 evaluations. NLG802 is a new chemical entity with patent coverage into 2036. We are also pursuing international patent coverage for NLG802.

NLG919

NLG919, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech. NLG919 seeks to inhibit the IDO enzyme directly and thereby prevent the metabolism of tryptophan into kynurenine. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, or the Genentech Agreement. The Genentech Agreement provided for the development and commercialization of NLG919. On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to NLG919, and such termination was effective December 6, 2017. As part of the partial termination, worldwide rights to NLG919 reverted back to the Company and Genentech granted us a license under certain of Genentech's intellectual property to develop and commercialize NLG919.

Under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/tryptophan-2,3-dioxygenase, or TDO, inhibitors. The research program ended in November 2016, and we received notice on May 9, 2018 that Genentech would not continue the collaboration with respect to next generation IDO/TDO inhibitors identified through the research program. The Genentech Agreement will terminate in its entirety no later than November 6, 2018.

Additional Product Candidates

Additional clinical-stage product candidates in our pipeline include two small molecules we acquired in 2017 from Daré Bioscience, Inc. (previously Cerulean Pharma Inc.) and two product candidates that utilize our HyperAcute® Cellular Immunotherapy technology. Our small molecule product, NLG207 (formerly CRLX101), is being evaluated in early clinical

development for patients with advanced solid malignancies. We have substantially reduced our financial commitment for CRLX301, the second asset acquired from Daré Bioscience, Inc., and have no future plans for the development of CRLX301. Additionally, we have substantially reduced our financial commitment for the HyperAcute Cellular Immunotherapy product candidates and have no plans to conduct additional clinical trials for such product candidates.

Ebola Vaccine Candidate

In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the Public Health Agency of Canada, or PHAC, and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of $30.0 million in October 2014, and in February 2015 we received a milestone payment of $20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. rVSVΔG-ZEBOV GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV GP from the U.S. BioMedical Advanced Research & Development Authority, or BARDA, and the Defense Threat Reduction Agency, or DTRA, totaling $52.1 million during 2016 and $67.0 million during 2014 and 2015. Funds of $2.1 million were de-obligated from the DTRA grant awards in 2017. We have received total awards of $118.8 million.

On April 26, 2018 we entered into an agreement with Merck, DTRA and BARDA to transfer the government grants from BARDA and DTRA to Merck. The transfer was completed in June 2018 and Merck has replaced us as the prime contractor on all such grants. As a result our grant revenues for the three and nine months ended September 30, 2018 have decreased as compared to the three and nine months ended September 30, 2017 and we expect to recognize no additional revenue from government contracts for the development of the rVSVΔG-ZEBOV GP vaccine product candidate subsequent to September 30, 2018.

Restructuring Charges

In July 2018, the Company completed an organizational review of its clinical programs and reduced its headcount by approximately 30% as compared to June 30, 2018 and made several changes to senior leadership effective July 26, 2018 in order to conserve its resources. Restructuring charges of $1.3 million were recorded during the three and nine months ended September 30, 2018 relating to this reorganization.

Our organizational realignment in July 2017 included a reduction of our workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Refer to Note 9 of the “Notes to Condensed Consolidated Financial Statements” of this Form 10-Q for more information.

Corporate Information

Founded in 1999, our principal executive office is located in Ames, Iowa, with additional offices located in Austin, Texas and Wayne, Pennsylvania. We have a clinical, research and development team dedicated to our pipeline of product candidates for patients with cancer and other diseases.

We incurred a net loss of $43.0 million for the nine months ended September 30, 2018. We expect to continue to incur losses over the next several years as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

Critical Accounting Policies and Significant Judgments and Estimates

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

Our Annual Report on Form 10-K for the year ended December 31, 2017, discusses our most critical accounting policies. Since December 31, 2017, there have been no material changes in the critical accounting policies discussed in our 2017 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 606 on January 1, 2018 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 4 of the "Notes to Condensed Consolidated Financial Statements" of this Form 10-Q. We do not believe that any other recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

Revenues. Revenues for the three months ended September 30, 2018 were $120,000, a decrease of $5.4 million from $5.5 million for the same period in 2017. The decrease in revenue was due to a decrease in grant revenue of $5.4 million, primarily due to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, offset by an increase of $17,000 in licensing revenue, due to higher billings to Merck.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2018 were $7.6 million, a decrease of $10.9 million from $18.5 million for the same period in 2017. The decrease was primarily due to reductions of $7.3 million in contract research and manufacturing spend, $2.5 million in clinical trial expense, $570,000 in personnel-related and stock compensation expense, $560,000 in supplies and licensing, and a $100,000 decrease in restructuring expense, offset by an increase of $70,000 in legal and consulting expense.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2018 were $7.6 million, a decrease of $320,000 from $7.9 million for the same period in 2017. The decrease was due primarily to reductions of $300,000 in restructuring expense, a decrease of $240,000 in legal and consulting expense, and a decrease of $10,000 in personnel-related and stock compensation expense, offset by an increase of $230,000 in supplies and other expense.

Income Tax Benefit. We recorded a $7.0 million and $119,000 income tax benefit for the three months ended September 30, 2018 and 2017, respectively. The increase in the benefit is due to amendments filed to change the allocation of income for certain states for the years ending December 31, 2014 and 2015. We received the full refund subsequent to September 30, 2018.

Net Loss. The net loss for the three months ended September 30, 2018 was $7.4 million compared to net loss of $20.6 million for the same period in 2017. The basic and diluted weighted-average common shares outstanding for the three months ended September 30, 2018 were 37,214,363, resulting in a basic and diluted loss per share of $0.20. For the three months ended September 30, 2017, the basic and diluted weighted-average common shares outstanding were 29,939,823, resulting in basic and diluted loss per share of $0.69.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Revenues. Revenues for the nine months ended September 30, 2018 were $12.3 million, a decrease of $6.3 million from $18.6 million for the same period in 2017. The decrease in revenue was due to a decrease in grant revenue of $7.0 million, primarily due to a decrease in billings under the government grant contracts as a result of the transfer of the government grant contracts which was completed in its entirety in June 2018, and an increase of $670,000 in licensing revenue.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2018 were $40.0 million, a decrease of $12.4 million from $52.4 million for the same period in 2017. The decrease was primarily due to reductions in contract research and manufacturing spend of $4.4 million, a decrease in supplies and other expense of $2.9 million, a decrease in personnel-related and stock compensation expense of $2.8 million, a decrease of $1.5 million in clinical trial expense, a decrease in licensing expense of $1.3 million, and a decrease in restructuring charges of $100,000, offset by a $646,000 increase in legal and consulting expenses.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2018 were $23.8 million, a decrease of $1.2 million from $25.0 million for the same period in 2017. The decrease was due primarily to a reduction in personnel-related spend of $1.5 million, a decrease in restructuring charges of $300,000, and a decrease in legal and consulting expense of $163,000, offset by increases in supplies and other expenses of $755,000.

Income Tax Benefit. There was $7.0 million in income tax benefit recorded for the nine months ended September 30, 2018, increased as compared to income tax benefit of $429,000 for the same period in 2017. The change of $6.6 million is primarily due to an amendment filed to change the allocation of income for certain states for the years ending December 31, 2014 and 2015. We received the full refund subsequent to September 30, 2018.

Net Loss. The net loss for the nine months ended September 30, 2018 was $43.0 million compared to net loss of $58.3 million for the same period in 2017. The basic and diluted weighted average common shares outstanding for the nine months ended September 30, 2018 were 37,178,542, resulting in a basic and diluted loss per share of $1.16. For the nine months ended September 30, 2017, the basic and diluted weighted average common shares outstanding were 29,462,226, resulting in basic and diluted loss per share of $1.98.

Liquidity and Capital Resources

As of September 30, 2018, we had cash and cash equivalents of $122.1 million. We have funded our operations principally through the private placement of equity securities and public offerings of common stock. To date, we have raised aggregate proceeds, net of offering costs, of $76.3 million from the issuance of convertible preferred stock prior to our IPO, and $145.3 million in net proceeds through our IPO and other public follow-on offerings through 2015. Additionally, we raised aggregate proceeds, net of offering costs, of $19.3 million through public at the market sales of common stock in 2017. In October 2017, we sold 5,750,000 shares of common stock in a public offering for aggregate net proceeds of $55.2 million after underwriters' discounts, commissions and other expenses of $3.7 million. We entered into a Sales Agreement with Cantor in March 2018 under which we may sell up to $60.0 million of our common stock in one or more placements at prevailing market prices in an ATM offering (the 2018 ATM Offering). As of September 30, 2018, no shares have been sold under the 2018 ATM Offering.

With the exception of the 2014 fiscal year, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. We anticipate that we will continue to generate operating losses as we incur expenses to complete our clinical trial programs for our product candidates, develop our pipeline and pursue regulatory approval of our product candidates.

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

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

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

We believe that our cash and cash equivalents on hand will be sufficient to fund our operations into the second half of 2021.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Nine Months Ended September 30,	
	2018	2017
Net cash used in operating activities	$ (36,622)	$ (31,070)
Net cash provided by investing activities	111	142
Net cash (used in) provided by financing activities	(136)	20,140
Net decrease in cash and cash equivalents	$ (36,647)	$ (10,788)

For the nine months ended September 30, 2018 and 2017, we used cash of $36.6 million and $31.1 million, respectively, for our operating activities. The increase in cash used in operating activities was primarily due to the decrease in research and development activity and changes in working capital for the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017.

For the nine months ended September 30, 2018 and 2017, our investing activities provided cash of $111,000 and $142,000, respectively. The cash provided by investing activities during the nine months ended September 30, 2018 was due to proceeds received from sales of property and equipment of $118,000, offset by the purchase of equipment of $7,000. The cash provided by investing activities during the nine months ended September 30, 2017 was due to the purchase of equipment of $43,000 offset by $185,000 in proceeds received from sales of property and equipment.

For the nine months ended September 30, 2018 and 2017, our financing activities used cash of $136,000 and provided cash of $20.1 million, respectively. The cash used in financing activities during the nine months ended September 30, 2018 was due to the issuance of common stock for net proceeds of $269,000 offset by net payments on long-term obligations and notes payable of $138,000 and repurchases of common stock of $267,000. The cash provided by financing activities during the nine months ended September 30, 2017 was primarily due to the sale and issuance of common stock for net proceeds of $20.6 million, offset by net payments on long-term obligations and notes payable of $185,000, and repurchase of common stock of $260,000.

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 September 30, 2018 and December 31, 2017, we had cash and cash equivalents of $122.1 million and $158.7 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. 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.

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 September 30, 2018. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of September 30, 2018, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. 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

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. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

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. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize indoximod, our business, financial condition and results of operations would be harmed.

The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. If we fail to complete any of these trials or fail to obtain regulatory approval, our ability to commercialize indoximod will be materially and adversely affected and our business, financial condition and results of operations would be harmed.

If we make changes to any of our product candidates, additional clinical trials may be required resulting in additional costs and delays.

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we

would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

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 of the clinical trials necessary to support an application with the FDA for approval to market any of our product candidates. Our current and future clinical trials may be delayed or terminated as a result of many factors, including:

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- 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 clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- 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 the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

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

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

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

Clinical trials for our product candidates require us to identify and enroll a large number of patients with the disease under investigation, or healthy volunteers willing to participate in certain trials. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a clinical trial, 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;
- size of the patient population;
- eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the product candidate under study;
- changes in the standard of care that make the trial as designed less attractive to clinicians and patients;
- availability of competing therapies and clinical trials, including announced clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- the results of clinical trials of other IDO pathway inhibitors;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

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. The FDA is not bound by the recommendations of an Advisory Committee, but it typically follows such recommendations. In addition, should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all.

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

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

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

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

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

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

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

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

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

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 Good Clinical Practice, or GCP, requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, requirements 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;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- 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;
- failure to demonstrate a benefit from using a drug;
- 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 indoximod, NLG802, NLG919, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

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

We are currently supplying indoximod, our lead IDO pathway inhibitor product candidate, in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L in support of a Phase 2 investigator-initiated clinical trial. Our Ebola vaccine product candidate was studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

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

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

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

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

Even if ultimately approved, indoximod, NLG802, NLG919, our Ebola vaccine product candidate or any other potential product we or our collaborators may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

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

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

We will need to acquire additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development and commercialization efforts. Currently, we have limited experience in preparing applications for marketing approval, commercial-scale manufacturing, managing large-scale information technology systems or managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources.

To do this effectively, we must:

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

We will need to increase our manufacturing capacity, which may include negotiating and entering into additional third-party agreements to meet our commercial manufacturing requirements.

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 these products ourselves.

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

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. 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 an adequate number of physicians to educate them about the attributes of 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 toward 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. The long-term loss of services of key executives 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 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. Additionally, our only significant facility is 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 rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

We do not possess all of the capabilities to fully commercialize any of our product candidates on our own. If we are unable to arrange for third-party manufacturing sources, or to do so on commercially reasonable terms, we may not be able to complete development of such product candidates or market them. In addition, we currently rely on our partner Merck for the supply of our Ebola vaccine product candidate and other third party manufacturers for our supply of indoximod, NLG802, and 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 indoximod, NLG802, NLG919, our Ebola vaccine product candidate or other finished products.

Any prolonged delay or interruption in the operations of 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 product candidates 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 meet market demand for any products that are approved for sale on a timely basis.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, failure of the third party to accept orders for supply of drug substance or drug product and the possibility of termination or nonrenewal of the agreement by the third-party based on its own business priorities and at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale-up manufacturing processes as needed, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for product candidates that may have been granted to us and for other regulatory action, including recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical studies. There are a small number of suppliers for certain capital equipment and raw materials that are used to manufacture our product candidates. Such suppliers may not sell this capital equipment or these raw materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of this capital equipment or these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Because of the complex nature of many of our early stage compounds and product candidates, our manufacturers may not be able to manufacture such compounds and product candidates at a cost or in quantities or in a timely manner necessary to develop and commercialize related products. If we successfully commercialize any of our product candidates, we may be required to establish or access large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. To meet our projected needs for commercial manufacturing in the event that one or more of our product candidates gains marketing approval, third parties with whom we currently work will need to increase their scale of production or we will need to secure alternate suppliers.

Furthermore, we do not currently have experience with the management of relationships related to commercial-scale contract manufacturing, and we may incur substantial costs to develop the capability to negotiate and enter into relationships with third-party contract manufacturers.

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

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

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.

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

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

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

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is 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 insurance (real, personal and business income) of nearly $11.6 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, development, testing, manufacturing, labeling, packaging, marketing, distribution, promotion 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 and effective in the case of a small-molecule pharmaceutical product, or

is safe, pure and potent in the case of a biologic, 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 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 trials 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. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, 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.

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. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

- warning letters;
- civil or criminal penalties;
- injunctions;
- suspension of or withdrawal of regulatory approval;
- total or partial suspension of any ongoing clinical trials or of production;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to approve pending applications for marketing approval of new products or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

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 continue to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals, among other things. 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. Noncompliance 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. Foreign regulatory authorities could also 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 whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistleblowing claim, even if without merit, could result in costly litigation or regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

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

In both the United States and foreign markets, sales of our proposed products will depend in part on the availability of coverage and reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. In addition, the process for determining whether a third party payer will provide coverage for a pharmaceutical typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payer will pay for the product once coverage is approved. Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare 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.

Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of healthcare. 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. 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, however, certain services rendered to clinical trial participants may be reimbursable by third-party payors for standard of care treatment if not otherwise reimbursed under the applicable clinical trial study budget.

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; our failure to comply with these laws could harm our results of operations and financial condition.

In addition to FDA restrictions on marketing of biopharmaceutical products, our operations may be directly, or indirectly through our relationships with healthcare providers, customers and third-party payers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute. These laws may impact, among other things, our proposed sales, and education programs, and these laws have been applied to restrict certain marketing practices in the biopharmaceutical industry. In addition, we may be subject to patient privacy regulation by both the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the following:

- The federal 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 the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.
- The federal civil False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the federal government a claim for payment or approval that is false or fraudulent or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 off-label promotion. Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.
- The federal Food, Drug and Cosmetic Act, or FDCA, prohibits, among other things, the adulteration or misbranding of drugs and medical devices.
- The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

- Analogous state laws and regulations include: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information and that require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that required that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order included a budget neutrality provision that required the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations that can be repealed to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Further, on February 24, 2017, President Trump issued an Executive Order requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. It is difficult to predict how these requirements will continue to be enforced, the extent to which they will continue to impact the FDA's ability to exercise its regulatory authority, and the negative impact they may have on our business.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, in the United States, the pharmaceutical industry has been affected by the passage of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, which, among other things, imposed new fees on entities that manufacture or import certain branded prescription drugs and expanded pharmaceutical manufacturer obligations to provide discounts and rebates to certain government programs. There have been judicial and congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Act includes a provision repealing, effective

January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress may consider other legislation to repeal and replace elements of the ACA.

In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Additionally, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2018, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the “Wholesale Acquisition Cost”, or list price, of that drug or biological product. Any of these initiatives could harm our ability to generate revenues.

In the future, there will likely continue to be proposals relating to the reform of the U.S. healthcare system, some of which could further limit coverage and reimbursement of drug products, including our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Individual states are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers 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 which pharmaceutical products and 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.

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 10 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act") was signed into law. The law, among other things, provides a federal framework for certain

patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative or administrative action, either in the United States or abroad.

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.

Failure to comply with existing or future data protection laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, or affect our or our partners' ability to offer our products and services in certain locations.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil and/or criminal penalties including if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

International data protection laws, including, without limitation, the European Union Directive 95/46/EC, or the Directive, and the European Union's General Data Protection Regulation, or the GDPR, that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the European Union, including in relation to use, collection, analysis and transfer of such personal information. These laws include several requirements relating to the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The Directive and the GDPR prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions.

Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with European Union data protection laws remains. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

Financial Risks

We have a history of net losses. We incurred a net loss for the years ended December 31, 2016 and 2017 and expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future.

We were profitable in the year ended December 31, 2014, primarily as a result of upfront payments under the Genentech Agreement and the Merck Agreement. We are not entitled to receive any additional upfront payments under these licensing or collaboration agreements. We do not expect any milestone or royalty payments under these or other agreements, if any, to be sufficient to make us profitable in future years. We incurred a loss of $43.0 million for the nine months ended September 30, 2018 and we do not expect to be profitable for the foreseeable future. We anticipate that we will continue to incur operating losses over the next several years as we continue our clinical development programs.

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

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

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution

capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost of manufacturing our product candidates and any products we commercialize;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- the potential requirement to repay our outstanding government provided loans;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing and receipt of revenues from existing or future products, if any; 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, develop our pipeline and pursue regulatory approval of our product candidates. We believe that our existing cash and cash equivalents will allow us to fund our operating plan in the near and medium term. 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 $350,000 to $4.3 million under our license agreements (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 is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

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

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

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

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

Through our subsidiary, BioProtection Systems Corporation, or BPS, we have received funding from multiple government agencies for our Ebola vaccine product candidate development efforts. There is no guarantee that we will receive sufficient, or any, future grant funding to meet our obligations related to our Ebola vaccine development or that we or Merck will succeed in developing an Ebola vaccine. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

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

For the three and nine months ended September 30, 2018, we have recorded a $7.0 million tax benefit. 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 (including the recently enacted U.S. federal income tax law changes), 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.

The recently enacted comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017 the Tax Act was signed into law. The Tax Act significantly revised the Internal Revenue Code of 1986, as amended and included, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted Tax Act. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Many of the products that we are attempting to develop and commercialize will be competing with existing therapies. In addition, a number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies both in the United States and abroad. Our competitors may utilize discovery technologies and techniques or collaborate with third parties in order to develop products more rapidly or successfully than we or our collaborators are able to do. Many of our competitors, particularly large pharmaceutical companies, have substantially greater financial, technical and human resources than we do. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with our competitors.

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Many companies have entered into the field of immuno-oncology and are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our product candidates. Most of our competitors possess substantially greater financial, technical and human resources than we possess. In addition, many of our competitors have significantly greater experience than we have in conducting preclinical and nonclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of drugs and manufacturing facilities. Accordingly, our competitors may succeed in obtaining regulatory approval for drugs more rapidly than we do. We expect to face growing competition for enrollment of patients in our clinical trials, which could delay or adversely affect our ability to complete such trials. We may also be adversely effected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

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

Our competitive position will also depend upon our ability to attract and retain qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often lengthy period between technological conception and commercial sales. We will require substantial capital resources to complete development of some or all of our products, obtain the necessary regulatory approvals and successfully manufacture and market our products. In order

to secure capital resources, we may elect to sell additional capital stock, which would dilute the holdings of existing stockholders. We may also attempt to obtain funds through research grants and agreements with commercial collaborators. However, these types of financings are uncertain because they are at the discretion of the organizations and companies that control the funds. Accordingly, we may not receive any additional funds from grants or collaborations.

Research and discoveries by others may result in breakthroughs that render indoximod, NLG802 and NLG919 product candidates, 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 future products, if any, may not be accepted in the marketplace and therefore, we may not be able to generate significant revenue, or any revenue.

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

Risks Relating to Our Arrangements with Third Parties

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

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, as well as our strategic collaborators and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Merck is responsible for clinical trials of our Ebola vaccine product candidate, we are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and with GCP 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 GCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or to commercialize the product candidate being tested in such trials, or may be delayed in doing so.

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

We are also dependent on Merck for the development of the product candidates that are the subject of the Merck Agreement. If the company does not succeed in advancing the product candidate to final approval, or decides to discontinue its collaboration with us, such failure or decision, could materially harm our business.

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

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

If we enter into a collaboration agreement we consider acceptable, including the Merck Agreement to develop and commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

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

Under the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it is terminating the Genentech Agreement with respect to NLG919 and gave additional notice in May 2018 that the remainder of the Agreement would terminate no later than November 6, 2018. Further, Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the development or commercialization efforts. The occurrence of any of these events could adversely affect the development or commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA in the future, 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 the process of seeking appropriate strategic collaborators, and such 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 them.

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

Our collaborations, including any future strategic collaborations we enter into, could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the Genentech Agreement and the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- strategic collaborators 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 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 thereunder 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.

Merck, which has sublicensed our Ebola vaccine product candidate, has received correspondence from Yale University asserting that it owns certain intellectual property rights with respect to the Ebola vaccine that they assert, among other things, may need to be licensed by Merck. We also received correspondence from Yale University relating to the research and construction of the Ebola vaccine product by our licensor PHAC. If Merck were required to pay royalties to Yale University, that could result in a reduction of Merck’s royalty obligations to us. If Merck otherwise suffered damages as a result of claims by Yale University, it is possible that Merck could seek indemnification from us.

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

We intend to rely on patent rights for our product candidates and any future product candidates. If we are unable to obtain or maintain exclusivity from the combination of these approaches, we may not be able to compete effectively in our markets.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors’ ability to obtain regulatory exclusivity and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technologies and product candidates.

We have sought to protect our proprietary position by filing patent applications related to our technologies and product candidates that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable, or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether

any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data exclusivity, for our product candidates, we may not be able to compete effectively, and our business and results of operations would be harmed.

We may not have sufficient patent term protections for our product candidates to effectively protect our business.

Patents have a limited term. In the United States, the statutory expiration of a patent is generally 20 years after it is filed. Additional patent terms may be available through a patent term adjustment process, resulting from the USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic medications.

Patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent or data exclusivity terms of our product candidates. We will likely rely on patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations, and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

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 filed patent applications in the United States that claim technology also claimed by us, and such applications were filed before the Leahy-Smith Act took effect, 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 becomes 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.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Relating to Our Exposure to Litigation

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

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and commercial sale of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death. In addition, healthy volunteers in our indoximod clinical trial or our Ebola vaccine product candidate clinical trial may suffer, or perceive themselves to suffer, personal injury or death related to the Ebola vaccine product candidates and may initiate legal action against us.

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our product candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 million in the aggregate for claims related to our Ebola vaccine product candidate. We additionally currently carry clinical trial coverage in lower aggregate amounts in local markets where our clinical trials are conducted on a selective, trial by trial basis. There can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any future products by us or our collaborators.

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

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

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

We are involved in a securities class-action litigation and are at risk of additional similar litigation in the future that could divert management's attention and adversely affect our business and could subject us to significant liabilities.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of securities. We are a party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading "Legal Proceedings." The defense of this litigation may increase our expenses and divert our management's attention and resources and any unfavorable outcome could have a material adverse effect on our business and results of operations. Any adverse determination in this litigation, or any amounts paid to settle this litigation could require that we make significant payments. In addition, we may in the future be the target of other securities class actions or similar litigation.

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, 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 those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- ◦ expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- ◦ the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- ◦ disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- • the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Merck;
- • additions or departures of key scientific or management personnel;
- • conditions or trends in the biotechnology and biopharmaceutical industries;
- • media attention, or changes in media attention, given to cancer and cancer treatment, the recent Ebola epidemic and efforts to develop treatments and vaccines for Ebola, or any other condition or disease that our product candidates are being developed to treat;
- • actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- • actual and anticipated fluctuations in our quarterly operating results;
- • the financial projections we may provide to the public, and any changes in these projections or our failure to meet these projections;
- • deviations from securities analysts' estimates or the impact of other analyst rating downgrades by any securities analysts who follow our common stock;
- • other events or factors, including those resulting from political uncertainty, 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. We are currently party to the securities class action litigation described in Part II, Item 1 of this Quarterly Report on Form 10-Q under the heading “Legal Proceedings.” This litigation and others like it that could be brought against us in the future 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 September 30, 2018, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 58.84% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after September 30, 2018. 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.

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 Global Market. 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, 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, 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 only 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 call special meetings;
- limitations on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

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

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

The holdings of our stockholders may be diluted, and the prices of our securities may decrease, by the exercise of outstanding stock options 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 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 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 our inception through December 31, 2017, 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 limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

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.

U.S. 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 one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

ITEM 1. LEGAL PROCEEDINGS

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint asserting claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs dido not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. On March 29, 2018, the Court dismissed the amended complaint for failure to state a claim, without prejudice, and gave the lead plaintiffs until May 4, 2018 to file any amended complaint attempting to remedy the defects in their claims. On May 4, 2018, the lead plaintiffs filed a second amended complaint asserting claims under the federal securities laws against the Defendants. Like the first amended complaint, the second amended complaint alleges that the Defendants made material false and/or misleading statements or omissions relating to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L that caused losses to the Company's investors. The lead plaintiffs did not quantify any alleged damages in the second amended complaint but, in addition to attorneys' fees and costs, they sought to recover damages on behalf of themselves and other persons who purchased or otherwise acquired the Company's stock during the putative class period of September 17, 2013 through May 9, 2016, inclusive, at allegedly inflated prices and purportedly suffered financial harm as a result. The Defendants filed a motion to dismiss the second amended complaint on July 31, 2018. The lead plaintiffs filed an opposition to the motion to dismiss the second amended complaint on September 14, 2018. The Defendants filed a reply in support of the motion to dismiss the second amended complaint on October 9, 2018. Oral argument was held on October 19, 2018, after which the Court reserved decision. The Company intends to continue defending the Securities Action vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation of federal securities law. The complaint also asserts state law claims against the Morrow Defendants for breaches of fiduciary duties, unjust enrichment, abuse of control, insider trading, gross mismanagement, and corporate waste, alleging that the Morrow Defendants made material misstatements or omissions related to the Phase 2 and 3 trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise finally resolved. Under the terms of the stay, the plaintiff in the Ely Action will be provided with any discovery that is provided in the Securities Action, and given an opportunity to participate in any mediation or settlement efforts in the Securities Action. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

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 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				
10.1	*	Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Merck Sharp & Dohme Corp., dated October 9, 2018				X
10.2	†	Separation and Release Agreement, dated as of July 26, 2018, between the Registrant and John B. "Jack" Henneman III				X
10.3	†	Separation and Release Agreement, dated July 26, 2018, between the Registrant and Brian Wiley				X
10.4	†	Employment Agreement, dated July 26, 2018, between the Registrant and Carl W. Langren				X
10.5	†	Employment Agreement, dated July 26, 2018, between the Registrant and Lori Lawley				X
10.6		For of Indemnity Agreement by and between the Company and its directors and executive officers	S-1/A	11/8/2011	10.11	
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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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.

* Indicates confidential treatment has been requested with respect to specific portions of this exhibit. Omitted portions have been filed with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 19434, as amended.

"The certifications attached as Exhibit 32.1 that accompany this 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.

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: November 2, 2018

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: November 2, 2018

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

Exhibit 10.1

AMENDMENT 3 TO
LICENSE AND COLLABORATION AGREEMENT

This third Amendment (this "**Amendment 3**") is effective as of the last date of signature (the "**Amendment Effective Date**"), and is entered into by and between MERCK SHARP & DOHME CORP., a corporation organized and existing under the laws of New Jersey ("**Merck**"), and BIOPROTECTION SYSTEMS CORPORATION**,** a corporation organized and existing under the laws of Delaware ("**NewLink**") and a wholly owned subsidiary of NEWLINK GENETICS CORPORATION, a corporation organized and existing under the laws of Delaware ("**NL**").

RECITALS:

WHEREAS, Merck and NewLink are parties to that certain License and Collaboration Agreement dated November 21, 2014, and further amended on December 5, 2017 and May 10, 2018 (the "**Agreement**"); and

WHEREAS, Merck and NewLink desire to further amend the Agreement as set forth herein.

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

1. The Parties agree to amend the listing of NewLink Third Party Agreements. In order to effect this amendment, Schedule 2.9.4 of the Agreement is deleted in its entirety and replaced with the revised Schedule 2.9.4 provided in this Amendment

2. The Parties acknowledge and agree the Transition Period of the Agreement has ended.

3. The Parties acknowledge and agree that Merck has requested that, for a period starting July 1, 2018 and ending May 10, 2019 (the "[*****] **Transition Period**"), NewLink maintains that certain agreement between [*] effective as of October 20, 2014, and subsequently amended February 27, 2015 and January 13, 2016, which concerns [*] (the "[*****]"). NewLink agrees it will use reasonable efforts to maintain the [*] for the duration of the Fisher Transition Period.

4. Beginning July 1, 2018, Merck shall reimburse NewLink for NewLink's reasonable expenses incurred in the course of maintaining the [*], including:
    a. amounts billed to NewLink under the [*] including the ongoing costs [*],
    b. expenses related [*] if reasonably required by [*]
    c. expenses related to any [*] if reasonably required by [*],
    d. consultant fees,
    e. plus the greater of:
        i. [*] of the total of such expenses, or
        ii. [*] per calendar quarter or any portion thereof.

    NewLink shall bill Merck quarterly and Merck shall remit payment within 30 days of the date of each invoice. All amounts due under this Amendment are in addition to any other amounts Merck

may owe NewLink, including, but not limited to, any amounts due to NewLink under the May 10, 2018 amendment referenced in the recitals to this Amendment above.

5. Throughout the [*] Transition Period, Merck shall provide periodic updates to NewLink regarding Merck's efforts to find [*]. NewLink also agrees to provide reasonable cooperation to Merck [*]. In the event it becomes apparent that [*] during the [*] Transition Period, for purposes of clarity, then commercially reasonable efforts shall include [*].

6. The [*] Transition Period will end upon the earlier of:
    a. written notice from Merck;
    b. [*], or
    c. May 10, 2019, unless extended as set forth in Amendment section 6 of this Amendment.

7. It is anticipated that Merck will make the necessary arrangements to [*] prior to termination of the [*] Transition Period. [*].

8. Provided that, as evidenced by the quarterly reports received by NewLink in accordance with Amendment section 3, Merck has made commercially reasonable efforts to [*], Merck may request in writing an extension of the [*] Transition Period. During any such extension after May 10, 2019, in addition to the reimbursement obligations set forth in Amendment section 2, Merck shall pay NewLink *] for each month of extension or any part thereof. Upon the conditions of this Section 6 being met, such extended period shall be part of the [*] Transition Period, and the remaining provisions of this Amendment shall apply.

9. Merck shall indemnify, defend and hold the NewLink Indemnitees harmless from and against any Liabilities arising, directly or indirectly out of or in connection with or relating to performance by any NewLink Indemnitee and/or any Third Party of the obligations set forth in this Amendment; except to the extent such Liabilities result from the gross negligence or willful misconduct of NewLink or other NewLink Indemnitees. THE SERVICES TO BE PERFORMED BY NEWLINK UNDER THIS AMENDMENT ARE FURNISHED AS IS, WHERE IS, WITH ALL FAULTS AND WITHOUT WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

10. Capitalized terms used and not defined herein shall have the meaning ascribed to such terms in the Agreement.

11. Except as specifically set forth in this Amendment, the Agreement will continue in full force and effect without change. If there is any conflict between the terms of this Amendment and the Agreement, this Amendment will govern.

12. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. In addition, this Amendment may be executed by facsimile or "PDF" and such facsimile or "PDF" signature shall be deemed to be an original.

13. This Amendment shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws or renvoi.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the Amendment Effective Date.

Merck Sharp & Dohme Corp. **Bioprotection Systems Corporation**

By: /s/ Benjamin Thorner By: /s/ Carl Langren

Name: Benjamin Thorner Name: Carl Langren

Title: SVP & Head of BD&L Title: Chief Financial Officer

Dated: 9/25/2018 Dated: 10/9/2018

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

Schedule 2.9.4

NewLink Third Party Agreements to be Assigned to Merck

[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
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[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

July 26, 2018

John B. Henneman, III

Re: Separation and Release Agreement

Dear Jack:

This letter sets forth the terms of the separation agreement (the "**Agreement**") that NewLink Genetics Corporation (the "**Company**") is offering to aid in your employment transition.

1. Transition and Separation Date.

(a) **Transition Period**. You hereby resign as Chief Financial Officer and Secretary of the Company, and from any other office or position you may hold with the Company or any affiliated entity, effective as of July 26, 2018. From such date through the "Separation Date" (as defined below) (the "**Transition Period**"), you will serve as the Company's Chief Administrative Officer with responsibility over the law and human resources functions of the Company, and will provide transition assistance over the finance function as may be requested by the Company's Chief Executive Officer or new Chief Financial Officer. The "**Separation Date**" shall be the earlier of November 9, 2018 or the date your employment with the Company ends pursuant to Section 9 of your Employment Agreement with the Company dated December 31, 2015 (the "**Employment Agreement**"). On the first regular payroll date after the Separation Date, the Company will pay you all accrued base salary and all remaining accrued but unused vacation earned for your services through the Separation Date, less applicable payroll deductions and withholdings. You are entitled to these payments regardless of whether or not you sign this Agreement.

(b) **Employment Agreement**. During the Transition Period, and except as modified by this Agreement, the terms of the Employment Agreement (including Section 4 (Base Salary) and Section 7 (Other Benefits) thereof) shall continue in effect; provided, however, that (i) Section 2 of the Employment Agreement shall not restrict you from service on boards of directors or engaging in activities outside the Company so long as such activities do not interfere with your responsibilities during the Transition Period (subject to your Employee Proprietary Information, Inventions, Non-Competition, and Non-Solicitation Agreement with the Company (the "**Proprietary Information Agreement**" attached hereto as **Exhibit A**)), and (ii) Section 9(g) and Section 10 of the Employment Agreement shall not apply.

2. Expense Reimbursements. You agree that, within forty-five (45) days of the Separation Date, you will submit to the Company your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for these expenses pursuant to its regular business practice.

3. Severance Benefits. In consideration for the general release of claims and the ADEA Waiver you are providing in Section 12 (Release of Claims; ADEA Waiver) of this Agreement, and for all other promises you are making and obligations you are undertaking by entering into this Agreement, allowing it to become fully effective and non-revocable, and for complying with its terms, the Company shall provide you with the severance payments and benefits (collectively, the "**Severance Benefits**") described below. Except as expressly provided otherwise, all cash benefits shall be paid subject to applicable payroll deductions and withholdings.

(a) Cash Severance.

(i) **Initial Severance Payment.** On the first regularly scheduled payroll pay date after the Effective Date (as defined in Section 12(e) (ADEA Waiver) of this Agreement), the Company will pay you a lump sum severance payment of $42,360.00 (the "**Initial Severance Payment**"), reflecting the difference between your annual salary before your voluntary July 2017 pay reduction, and your current annual salary.

(ii) **2018 Bonus.** The Company also will pay you a bonus for your 2018 services (the "**Bonus Payment**") calculated as follows: (i) $152,496 (representing eleven-twelfths of your Target Bonus as set forth in your Employment Agreement based on your current salary level), multiplied by the percentage completion of the Company's 2018 corporate goals ("**2018 Goals**") (and assuming, for these purposes, 100% completion of your individual goals). You understand and agree that the Board of Directors of the Company (the "**Board**") may revise the 2018 Goals at any time to reflect developments during the course of 2018, and that the Board's decision regarding any revisions to its 2018 Goals, and/or the percentage completion of those Goals, shall be final and binding, provided that any such changes result in a percentage of completion no lower than that determined for incumbent executives. The Bonus Payment will be paid to you at the same time 2018 bonuses are paid to other executives, but not later than March 15, 2019.

(iii) **Continuation Payments.** Consistent with the severance provisions set forth in Sections 9(g) and 11 of the Employment Agreement, the Company will pay you cash severance in the form of continuing payment of your current base salary for a period of twelve (12) months, paid on the Company's customary payroll schedule, beginning on the first payroll schedule after the Separation Date (the "**Salary Continuation Payments**"); *provided*, *however*, that, as required by Section 409A of the Internal Revenue Code of 1986, as amended (the **"Code"**) and the regulations and other guidance thereunder and any state law of similar effect (collectively **"Section 409A"**), the Salary Continuation Payments shall not commence until the first regularly scheduled payroll date that is six (6) months after the Separation Date (the "**Deferred Initial Payment Date**"), on which date the Company will pay to you (or your beneficiaries) a lump sum amount equal to the sum of the Salary Continuation Payments otherwise scheduled to be made prior to the Deferred Initial Payment Date. The remaining Salary Continuation Payments shall be paid on the Company's regular payroll payment dates thereafter until paid in full. No interest will be paid to you on any amounts for which payment is delayed pursuant to the foregoing provision. Notwithstanding the foregoing, in the event that Separation Date occurs prior to November 9, 2018 for any reason other than your resignation, the period of Salary Continuation Payments shall be extended by the number of days between the Separation Date and November 9, 2018.

(b) Healthcare Continuation Coverage Payments.

(i) COBRA Premiums. As an additional severance benefit, if you timely elect continued COBRA coverage under the Company's group health plan (including any dental and/or vision coverage), the Company will reimburse you for the COBRA premiums you pay to continue such coverage (including coverage for any eligible dependents, if applicable) (the "**COBRA Premiums**") through the period (the "**COBRA Premium Period**") starting on the Separation Date and ending on the earliest to occur of: (i) expiration of the period of Salary Continuation Payments (as such period may be extended pursuant to Section 3(a)(iii) above); (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event you become covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you shall immediately provide written notification of such event to the Company's Human Resources Manager. You

must submit to the Company documentary proof of the fact and amount of any COBRA Premiums paid within sixty (60) days of making such payment, in order to be reimbursed hereunder. Reimbursements will be paid within thirty (30) days of submission.

(ii) Alternative Cash Payments in Lieu of COBRA Premiums. Notwithstanding the foregoing, if the Company determines, in its reasonable discretion, that it cannot reimburse the COBRA Premiums without a substantial risk of violating applicable law (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), the Company instead shall pay you, on the first day of each calendar month following such determination, a fully taxable cash payment which, after taxes, is equal to the COBRA Premium amount the Company would have otherwise reimbursed you for that month (assuming a 37% tax rate) (such amount, the "**Alternative Cash Payment**"), for the remainder of the COBRA Premium Period. You may, but are not obligated to, use such Alternative Cash Payments toward the cost of COBRA premiums.

(c) Equity. You have been granted options to purchase shares of the Company's common stock (the "**Options**") and certain restricted stock units (the "**RSUs**," and together with the Options, the "**Awards**") pursuant to the Company's 2009 Equity Incentive Plan (the "**Plan**"). Under the terms of the applicable governing agreements and Plan documents, vesting of any unvested Awards would cease on the Separation Date. As an additional severance benefit, the Company will: (i) accelerate the vesting of the outstanding and unvested Awards set forth on Exhibit B (the "**Subject Awards**") so that you are credited with an additional twelve (12) months of vesting as of the Separation Date (or for the period of Salary Continuation Payments if longer due to extension of the period of Salary Continuation Payments pursuant to Section 3(a)(iii) above) (the "**Accelerated Vesting**"); and (ii) extend the exercise period under the governing agreements and Plan documents so that you have until November 8, 2020 to exercise any vested Subject Awards (including any Awards accelerated hereunder) (the "**Extended Exercise Period**"). The vesting of your other Awards will cease as of the Separation Date and the exercise period of such Awards will remain unchanged. To the extent that any performance criteria under any Award have not been satisfied as of the Separation Date, such Awards shall terminate as of the Separation Date. Except as expressly provided in this Section, the Options and RSUs will continue to be governed by the terms of the governing agreements and Plan documents. You acknowledge and agree that the Extended Exercise Period may convert any portion of the Options that were incentive stock options into non-qualified stock options, thereby changing their tax treatment; and you should seek advice from your own tax advisors about this extension.

(d) 409A Compliance. It is intended that the Severance Benefits provided to you hereunder comply with, or be exempt from, Section 409A, and that any ambiguities herein will be interpreted to so comply and/or be exempt from Section 409A. It is intended that all of the benefits and payments under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be interpreted accordingly. To the extent not so exempt, this Agreement (and any definitions hereunder) will be interpreted in a manner that complies with the Section 409A requirements. For purposes of Section 409A, your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. If the period of time you could sign this Agreement crosses over two calendar years, the Agreement shall be deemed to have become effective on the last possible date it could become effective.

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

5. Proprietary Information, Non-Solicitation and Non-Competition Obligations. You acknowledge and agree to abide by your continuing obligations under the Proprietary Information Agreement after the Separation Date to the extent provided therein, including but not limited to your obligations not to use or disclose any confidential or proprietary information of the Company, to comply with your post-employment non-competition and non-solicitation restrictions and to return company property; provided that you shall be permitted to purchase and retain your Company-provided cellphone, computer and any related equipment for their respective book value.

6. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; provided, however, that: (a) you may disclose this Agreement in confidence to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law. Nothing herein shall alter any corporate or other reporting right or obligations applicable to the Company.

7. Non-Disparagement. Both you and the Company (through its officers and directors only, and only for so long as they serve in such capacities) agree not to disparage the other party, and the other party's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that both you and the Company may respond accurately and fully to any question, inquiry or request for information from the Company's Chief Executive Officer or any member of the Board or when required by legal process.

8. Public Statements. Both the Company and you shall respond to third party inquiries, and the Company shall issue a press release, effectively stating that you have resigned from your position as Chief Financial Officer on the date set forth above. The content of such press release will be as mutually agreed upon by you and the Company.

9. References. In response to any request for references from a prospective employer, the Company will verify only your last job title and dates of employment.

10. Cooperation.

(a) **Transition Briefings.** Through October 31, 2019, you agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, transitioning any work relationships and providing oral and written briefings (as requested) with respect to any past or present work activities and institutional knowledge, to such other persons as may be designated by the Company. You agree to make yourself available to respond to such inquiries with reasonable promptness, either telephonically or by email (as requested), unless the Company requests that you come to the Company for such discussion or to review certain documents or materials related to the inquiry. The Company will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding forgone wages, salary,

or other compensation), and will make reasonable efforts to accommodate your schedule.

(b) **No Voluntary Adverse Assistance.** You agree that you will not voluntarily provide assistance, information or advice, directly or indirectly (including through agents or attorneys), to any third party (including both persons and entities) in connection with any claim or cause of action of any kind brought against, or being prepared against, the Company by any third party, nor shall you induce or encourage any person or entity to bring such claims; *provided*, *however*, that nothing herein shall limit or restrict your right to engage in any of the protected activities described in Section 13 (Protected Rights) below.

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

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

12. Releases of Claims. On the Separation Date, and subject to the parties' re-execution of the Agreement as of such date, the following releases (the "Releases") shall become effective.

(a) Henneman Release of Claims. In exchange for the Severance Benefits, including the Initial Severance Payment, the Salary Continuation Payments, the Bonus, the reimbursement of your COBRA Premiums (or Alternative Cash Payments), the Accelerated Vesting, the Extended Exercise Period, and all other consideration provided to you by the Company under this Agreement that you would not otherwise be entitled to receive (the "**Release Consideration**"), you agree to the terms below.

(i) **General Release**. You hereby generally and completely release the Company and its parent or subsidiary entities, successors, predecessors and affiliates, and its and their directors, officers, employees, consultants, shareholders, agents, attorneys, insurers, affiliates and assigns (collectively, the "**Released Parties**") of and from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or on the date you sign this Agreement (collectively, the "**Released Claims**").

(ii) **Scope of Release.** The Released Claims include, but are not limited to: (1) all claims arising from or in any way related to your employment with the Company, or the termination of that employment; (2) all claims related to your compensation or benefits from the Company (except as expressly provided in this Agreement), including but not limited to salary, bonuses, commissions, vacation pay, PTO, expense reimbursement, severance pay, fringe benefits, profit sharing, stock, stock options, or any other ownership or equity interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing, including but not limited to any claims arising under or based on your initial employment offer letter or subsequent Employment Agreement (including claims for severance benefits thereunder); (4) all tort claims, including but not

limited to claims for battery, negligence, fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims in all jurisdictions, including but not limited to claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal Family and Medical Leave Act, the Equal Pay Act of 1963, the Fair Labor Standards Act, the Age Discrimination in Employment Act of 1967, as amended by the Older Workers Benefit Protection Act (together, the "**ADEA**"), the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act (and all similar state and local laws), the Iowa Civil Rights Act of 1965, the Iowa Wage Payment Collection Law, the Texas Commission on Human Rights Act, the Texas Payday Law, the Texas Labor Code, and any statute or regulation administered by the Texas Workforce Commission.

(iii) **Excluded Claims.** Notwithstanding the foregoing, the following are not included in the Released Claims (the "**Excluded Claims**"): (1) rights to apply for unemployment insurance benefits; (2) rights to workers' compensation disability benefits, claims and payments, if applicable; (3) rights with respect to outstanding equity awards granted to you by the Company; (4) any rights or claims for indemnification pursuant to any written indemnification agreement with the Company to which you are a party, or under Company bylaws or articles, or under applicable law; (5) any rights to coverage under any directors and officers liability insurance policy maintained by the Company; (6) any rights which are not waivable as a matter of law; and (7) any claims for breach of this Agreement. You represent and warrant that, other than the Excluded Claims, you are not aware of any claims you have or may have against any of the Released Parties that are not included in the Released Claims.

(b) ADEA Waiver. You further specifically agree that, as part of the Released Claims, you are releasing any claims that you could assert under the ADEA (the **"ADEA Waiver"**). You acknowledge that: you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA; that the Release Consideration is being given in partial consideration for the ADEA Waiver; and that the Release Consideration is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (1) this ADEA Waiver does not apply to any rights or claims that arise after the date you sign this Agreement; (2) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (3) you have forty-five (45) days to consider this Agreement (although you may choose voluntarily to sign it earlier); (4) you have seven (7) days following the date you sign this Agreement to revoke the Agreement (in a written revocation provided to and received by the Company's CEO within the 7-day revocation period); and (5) the Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement, provided that you have not timely revoked it (the "**Effective Date**"). You understand and agree that, if you revoke the ADEA Waiver, you will not be entitled to the Release Consideration.

(c) Company Release of Claims. In exchange for you entering into this Agreement, including providing the releases of claims and the ADEA Waiver set forth above, the Company hereby generally and completely releases you of and from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or on the date the Company signs this Agreement; provided, however, that nothing herein shall release or waive: (1) any rights the Company has under this Agreement or the Proprietary Information Agreement (attached as Exhibit A); (2) any claims arising out of your obligations to protect and not to disclose or make unauthorized use of any of the Company's confidential and proprietary information, including but not limited to claims under the Uniform Trade Secret Act or the Proprietary Information Agreement; or (3) any claims (whether direct or for indemnification or contribution) arising from any

willful material misconduct by you which constitutes theft, fraud, embezzlement, conversion of a business opportunity, or unlawful harassment. The Company hereby represents that it is not aware of any actual or potential claim against you that would be excluded from the foregoing release pursuant to either clauses (2) or (3) above.

13. Protected Rights. Nothing in this Agreement shall prevent you from challenging the validity of the release of claims provided herein in a legal or administrative proceeding. You further understand that nothing in this Agreement (including, without limitation, Section 6 (Confidentiality), Section 7 (Non-Disparagement) and Section 12 (Releases of Claims) above): limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"); prevents any party from providing information or disclosing the fact or terms of this Agreement as part of any government investigation: or prohibits any party from reporting possible violations of law or regulation to any Government Agencies or self-regulating entity under applicable law (including, but not limited to, the U.S. Securities and Exchange Commission's Whistleblower Rule, of Section 21F of the U.S. Securities Exchange Act of 1934, as amended). While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to the maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any of the Released Claims and any rights you have waived by signing this Agreement.

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

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

To accept the terms set forth above (except for Section 12 hereof), please sign and date this

Agreement and return the fully-executed Agreement to the Company by July 26, 2018. In addition, the Severance Benefits and the Releases are subject to your re-execution of this Agreement on the Separation Date. The Releases in Sections 12(c) shall become effective upon re-execution of this Agreement by that Company as of the Separation Date.

We wish you the best in your future endeavors.

Sincerely,

NewLink Genetics Corporation

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

Understood, Accepted and Agreed:

/s/ John B. Henneman, III
John B. Henneman, III

7/26/2018
Date

Re-Executed as of Separation Date:

NewLink Genetics Corporation

By: _____
Authorized Signatory

_____
Date

_____
John B. Henneman, III

_____
Date

Exhibit A -Proprietary Information Agreement

Exhibit B -Options and RSUs Subject to Twelve-Month Acceleration and Extended Exercise Period

Exhibit A

Proprietary Information Agreement

Exhibit B

Options Subject to Twelve-Month Acceleration and Extended Exercise Period

Grant Date	Grant Number	Options	Option Price
10/1/2014	100836	17,428	22.95
10/1/2014	100836N	191,822	22.95
1/2/2015	100941	136	43.65
1/2/2015	100941N	6,364	43.65
1/4/2016	101037	3,674	34.73
1/4/2016	101037N	42,677	34.73
8/9/2016	101242N	150,000	10.78
1/3/2017	101382	7,731	10.55
1/3/2017	101382N	61,019	10.55
1/3/2017	800008	17,188	10.55
1/3/2017	800011	17,187	10.55
1/3/2017	800009	17,188	10.55
1/3/2017	800010	17,187	10.55
3/9/2018	800014-1	14,625	7.85
3/9/2018	800014-1N	46,375	7.85
3/9/2018	800014-2	10,163	7.85
3/9/2018	800014-5	15,250	7.85
3/9/2018	800014-6	15,250	7.85
3/9/2018	800014-4	10,174	7.85
3/9/2018	800014-3	10,163	7.85

RSUs Subject to Twelve-Month Acceleration and Extended Exercise Period

Award Date	Award Number	RSUs
10/1/2014	300042	10,198
1/2/2015	300045	500
1/4/2016	300070	8,101

July 26, 2018

Brian Wiley

Re: Separation and Release Agreement

Dear Brian:

This letter sets forth the terms of the separation agreement (the "**Agreement**") that NewLink Genetics Corporation (the "**Company**") is offering to aid in your employment transition.

1. Separation Date. You hereby resign as Chief Commercial Officer of the Company, and from any other office or position you may hold with the Company or any affiliated entity, effective as of July 27, 2018. Within six (6) days after the Separation Date, the Company will pay you all accrued base salary and all remaining accrued but unused vacation earned for your services through the Separation Date, less applicable payroll deductions and withholdings. You are entitled to these payments regardless of whether or not you sign this Agreement.

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

3. Severance Benefits. In consideration for the general release of claims and the ADEA Waiver you are providing in Section 13 (Release of Claims; ADEA Waiver) of this Agreement, and for all other promises you are making and obligations you are undertaking by entering into this Agreement, allowing it to become fully effective and non-revocable, and for complying with its terms, the Company shall provide you with the severance payments and benefits (collectively, the "**Severance Benefits**") described below. Except as expressly provided otherwise, all cash benefits shall be paid subject to applicable payroll deductions and withholdings.

(a) **Cash Severance.**

(i) **Initial Severance Payment.** On the first regularly scheduled payroll pay date after the Effective Date (as defined in Section 13(e) (ADEA Waiver) of this Agreement), the Company will pay you a lump sum severance payment of $18,535 (the "**Initial Severance Payment**"), reflecting the difference between your annual salary before your voluntary July 2017 pay reduction, and your current annual salary, for a period of six months.

(ii) **2018 Bonus.** The Company also will pay you a bonus for your 2018 services (the "**Bonus Payment**") calculated as follows: (i) $68,116 (representing seven-twelfths of your Target Bonus as set forth in your Employment Agreement based on your current salary level), multiplied by the percentage completion of the Company's 2018 corporate ("**2018 Goals**"). The 2018 Goals were established by the Board in March 2018. You understand that the Board's decision regarding the attainment of those Goals, shall be final and binding. The Bonus Payment will be paid to you no later than the time 2018 bonuses are paid to other executives, and in any event not later than March 15, 2019.

(iii) **Continuation Payments.** Consistent with the severance provisions set

forth in Sections 9(g) and 11 of your Employment Agreement with the Company dated January 4 2016 (the "**Employment Agreement**"), The Company will pay you cash severance equal to $166,815, representing the base salary provided in your Employment Agreement, after giving effect to the reduction by the Amendment dated July 26, 2017, for a period of six (6) months (the "**Salary Continuation Payment**"). As required by Section 409A of the Internal Revenue Code of 1986, as amended (the **"Code"**) and the regulations and other guidance thereunder and any state law of similar effect (collectively **"Section 409A"**), the Salary Continuation Payment shall be paid upon the first regularly scheduled payroll date that is six (6) months after the Separation Date, on which date the Company will pay to you (or your beneficiaries) a lump sum amount equal to the sum of the Salary Continuation Payment. No interest will be paid to you on any amounts for which payment is delayed pursuant to the foregoing provision.

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

(i) **COBRA Election**. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you may be eligible to continue your group health insurance benefits at your own expense after the Separation Date.

(ii) **COBRA Premiums**. As an additional severance benefit, if you timely elect continued coverage under COBRA, the Company will reimburse you for the COBRA premiums you pay to continue your basic medical coverage (including coverage for any eligible dependents, if applicable, but excluding dental and vision insurance coverage) (the "**COBRA Premiums**") through the period (the "**COBRA Premium Period**") starting on the Separation Date and ending on the earliest to occur of: (i) six (6) months after the Separation Date; (ii) the date you become eligible for group health insurance coverage through a new employer; or (iii) the date you cease to be eligible for COBRA continuation coverage for any reason, including plan termination. In the event you become covered under another employer's group health plan or otherwise cease to be eligible for COBRA during the COBRA Premium Period, you shall immediately provide written notification of such event to the Company's Human Resources Manager. You must submit to the Company documentary proof of the fact and amount of any COBRA Premiums paid within sixty (60) days of making such payment, in order to be reimbursed hereunder. Reimbursements will be paid within thirty (30) days of submission.

(iii) **Alternative Cash Payments in Lieu of COBRA Premiums**. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot reimburse the COBRA Premiums without a substantial risk of violating applicable law (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), the Company instead shall pay you, on the first day of each calendar month following such determination, a fully taxable cash payment which, after taxes, is equal to the COBRA Premium amount the Company would have otherwise reimbursed you for that month (assuming a 35% tax rate) (such amount, the "**Alternative Cash Payment**"), for the remainder of the COBRA Premium Period. You may, but are not obligated to, use such Alternative Cash Payments toward the cost of COBRA premiums.

(c) **Equity.** You have been granted options to purchase shares of the Company's common stock (the "**Options**") and certain restricted stock units (the "**RSUs**," and together with the Options, the "**Awards**") pursuant to the Company's 2009 Equity Incentive Plan (the "**Plan**"). Under the terms of the applicable governing agreements and Plan documents, vesting of any unvested Awards would cease on the Separation Date. As an additional severance benefit, the Company will (i) accelerate the

vesting of the outstanding and unvested Awards set forth on Exhibit B (the "**Subject Awards**") so that you are credited with an additional twelve (12) months of vesting as of the Separation Date (the "**Accelerated Vesting**"); and (ii) extend the exercise period under the governing agreements and Plan documents so that you have one (1) year from the Separation Date to exercise any vested Subject Awards (including any Awards accelerated hereunder) (the "**Extended Exercise Period**"). To the extent that any performance criteria under any Award have not been satisfied as of the Separation Date, such Awards shall terminate as of the Separation Date. Except as expressly provided in this Section, the Options and RSUs will continue to be governed by the terms of the governing agreements and Plan documents. You acknowledge and agree that the Extended Exercise Period may convert any portion of the Options that were incentive stock options into non-qualified stock options, thereby changing their tax treatment; and you should seek advice from your own tax advisors about this extension.

(d) **409A Compliance.** It is intended that the Severance Benefits provided to you hereunder comply with, or be exempt from, Section 409, and that any ambiguities herein will be interpreted to so comply and/or be exempt from Section 409A. It is intended that all of the benefits and payments under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be interpreted accordingly. To the extent not so exempt, this Agreement (and any definitions hereunder) will be interpreted in a manner that complies with the Section 409A requirements. For purposes of Section 409A, your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. If the period of time you could sign this Agreement crosses over two calendar years, the Agreement shall be deemed to have become effective on the last possible date it could become effective.

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

5. Return of Company Property. No later than the close of business on the Separation Date, you shall return to the Company all Company documents (and all copies thereof) and other Company property or information in your possession or control (collectively, "**Company Property**"), including, but not limited to: Company hardcopy and softcopy files, databases, notes, emails, correspondence, financial and operational information, current or potential customer lists and contact information, product and services information, research and development information, drawings, records, plans, forecasts, reports, payroll information, spreadsheets, studies, analyses, compilations of data, proposals, agreements, sales and marketing information, personnel information, specifications, code, software, electronically or computer-recorded information, tangible property and equipment (including, but not limited to, computing and communications devices, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company and all reproductions thereof in whole or in part and in any medium. You shall make a diligent search to locate any such Company Property by the close of business on the Separation Date. In addition, if you have used any personally owned computing or communication device, server, or e-mail system to receive, store, review, prepare or transmit any confidential or

proprietary data, materials or information of the Company, then within five (5) business days after the Separation Date, you shall permanently delete and expunge such confidential or proprietary information from those systems without retaining any reproductions (in whole or in part); and you agree to make any such device or system available for inspection and analysis by the Company, upon its reasonable request, in order to permit the Company to determine whether you are in compliance with this provision. ***Your timely compliance with the provisions of this Section is a precondition to your receipt of the Severance Benefits and other benefits provided hereunder.***

6. Proprietary Information, Non-Solicitation and Non-Competition Obligations. You acknowledge and agree to abide by your continuing obligations under your Employee Proprietary Information, Inventions, Non-Competition, and Non-Solicitation Agreement with the Company (the "**Proprietary Information Agreement**" attached hereto as **Exhibit A**), effective as of the beginning of your employment with the Company and continuing after the Separation Date, including but not limited to your obligations not to use or disclose any confidential or proprietary information of the Company and to comply with your post-employment non-competition and non-solicitation restrictions.

7. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; provided, however, that: (a) you may disclose this Agreement in confidence to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law. Nothing herein shall alter any corporate or other reporting right or obligations applicable to the Company.

8. Non-Disparagement. Both you and the Company (through its officers and directors only, and only for so long as they serve in such capacities) agree not to disparage the other party, and the other party's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that both you and the Company may respond accurately and fully to any question, inquiry or request for information when required by legal process.

9. Public Statements. Both the Company and you shall respond to third party inquiries, and the Company shall issue a press release, effectively stating that you have resigned from your position as Chief Commercial Officer, and from your employment with the Company, effective as of the Separation Date. The content of such press release will be mutually agreed.

10. References. In response to any request for references from a prospective employer, the Company will verify only your last job title and dates of employment.

11. Cooperation.

(a) Transition Briefings. Prior to and after the Separation Date, you agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, transitioning any work relationships and providing oral and written briefings (as requested) with respect to any past or present work activities and institutional knowledge, to such other persons as may be designated by the Company. You agree to make yourself available to respond to such inquiries with reasonable promptness, either telephonically or by email (as requested), unless the Company requests that you come to the Company for such discussion or to review certain documents or materials related to the inquiry.

(b) No Voluntary Adverse Assistance. You agree that you will not voluntarily provide assistance, information or advice, directly or indirectly (including through agents or attorneys), to any third party (including both persons and entities) in connection with any claim or cause of action of any kind brought against, or being prepared against, the Company by any third party, nor shall you induce or encourage any person or entity to bring such claims; *provided*, *however*, that nothing herein shall limit or restrict your right to engage in any of the protected activities described in Section 14 (Protected Rights) below.

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

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

13. Release of Claims. In exchange for the Severance Benefits, including the Salary Continuation Payments, the reimbursement of your COBRA Premiums (or Alternative Cash Payments), the Accelerated Vesting, and all other consideration provided to you by the Company under this Agreement that you would not otherwise be entitled to receive (the "**Release Consideration**"), you agree to the terms below.

(a) General Release. You hereby generally and completely release the Company and its parent or subsidiary entities, successors, predecessors and affiliates, and its and their directors, officers, employees, consultants, shareholders, agents, attorneys, insurers, affiliates and assigns (collectively, the "**Released Parties**") of and from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or on the date you sign this Agreement (collectively, the "**Released Claims**").

(b) Scope of Release. The Released Claims include, but are not limited to: (1) all claims arising from or in any way related to your employment with the Company, or the termination of that employment; (2) all claims related to your compensation or benefits from the Company (except as expressly provided in this Agreement), including but not limited to salary, bonuses, commissions, vacation pay, PTO, expense reimbursement, severance pay, fringe benefits, profit sharing, stock, stock options, or any other ownership or equity interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing, including but not limited to any claims arising under or based on your initial employment offer letter or subsequent Employment Agreement (including claims for severance benefits thereunder); (4) all tort claims, including but not limited to claims for battery, negligence, fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims in all jurisdictions, including but not limited to claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964, the federal Americans with Disabilities Act of 1990, the federal

Family and Medical Leave Act (, the Equal Pay Act of 1963, the Fair Labor Standards Act, the Age Discrimination in Employment Act of 1967, as amended by the Older Workers Benefit Protection Act (together, the "**ADEA**"), the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act (and all similar state and local laws), the Iowa Civil Rights Act of 1965, the Iowa Wage Payment Collection Law, the Texas Commission on Human Rights Act, the Texas Payday Law, the Texas Labor Code, and any statute or regulation administered by the Texas Workforce Commission.

(c) Excluded Claims. Notwithstanding the foregoing, the following are not included in the Released Claims (the "**Excluded Claims**"): (1) rights to apply for unemployment insurance benefits; (2) rights to workers' compensation disability benefits, claims and payments, if applicable; (3) any rights or claims for indemnification pursuant to any written indemnification agreement with the Company to which you are a party, or under Company bylaws or articles, or under applicable law; (4) any rights which are not waivable as a matter of law; or (5) any claims for breach of this Agreement. You represent and warrant that, other than the Excluded Claims, you are not aware of any claims you have or may have against any of the Released Parties that are not included in the Released Claims.

(d) ADEA Waiver. You further specifically agree that, as part of the Released Claims, you are releasing any claims that you could assert under the ADEA (the **"ADEA Waiver"**). You acknowledge that: you are knowingly and voluntarily waiving and releasing any rights you have under the ADEA; that the Release Consideration is being given in partial consideration for the ADEA Waiver; and that the Release Consideration is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised, as required by the ADEA, that: (1) this ADEA Waiver does not apply to any rights or claims that arise after the date you sign this Agreement; (2) you should consult with an attorney prior to signing this Agreement (although you may choose voluntarily not to do so); (3) you have forty-five (45) days to consider this Agreement (although you may choose voluntarily to sign it earlier); (4) you have seven (7) days following the date you sign this Agreement to revoke the Agreement (in a written revocation provided to and received by the Company's CEO within the 7-day revocation period); and (5) the Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after you sign this Agreement, provided that you have not timely revoked it (the "**Effective Date**"). You understand and agree that, if you revoke the ADEA Waiver, you will not be entitled to the Release Consideration.

14. Protected Rights. Nothing in this Agreement shall prevent you from challenging the validity of the release of claims provided herein in a legal or administrative proceeding. You further understand that nothing in this Agreement (including, without limitation, Section 7 (Confidentiality), Section 8 (Non-Disparagement) and Section 13 (Releases of Claims) above): limits your ability to file a charge or complaint with the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission ("**Government Agencies**"); prevents any party from providing information or disclosing the fact or terms of this Agreement as part of any government investigation: or prohibits any party from reporting possible violations of law or regulation to any Government Agencies or self-regulating entity under applicable law (including, but not limited to, the U.S. Securities and Exchange Commission's Whistleblower Rule, of Section 21F of the U.S. Securities Exchange Act of 1934, as amended). While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to the maximum extent permitted by law, you are otherwise waiving any

and all rights you may have to individual relief based on any of the Released Claims and any rights you have waived by signing this Agreement.

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

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

To accept the terms set forth above, please sign and date this Agreement and return the fully-executed Agreement to the Company within 21 days after the Separation Date.

We wish you the best in your future endeavors.

Sincerely,

NewLink Genetics Corporation

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

Exhibit A -Proprietary Information Agreement

Understood and Agreed:

/s/ Brian Wiley
Brian Wiley

7/26/2018
Date

Exhibit A

Proprietary Information Agreement

Exhibit B

Options Subject to Twelve-Month Acceleration and Extended Exercise Period

Grant Date	Grant Number	Options	Option Price
1/14/2013	100687	29693	11.79
1/14/2013	100687N	174307	11.79
8/9/2016	101243	0	10.78
8/9/2016	101243N	30000	10.78
1/3/2017	101383	9787	10.55
1/3/2017	101383N	65213	10.55
3/9/2018	800016-1	14076	7.85
3/9/2018	800016-1N	40924	7.85
3/9/2018	800016-2	9163	7.85
3/9/2018	800016-4	9174	7.85
3/9/2018	800016-3	9163	7.85
3/9/2018	800016-5	13750	7.85
3/9/2018	800016-6	13750	7.85

RSUs Subject to Twelve-Month Acceleration and Extended Exercise Period

Award Date	Award Number	RSUs
1/2/2015	300052	1,850
1/4/2016	300076	3,191

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made as of this 26th day of July, 2018, by and between NewLink Genetics Corporation (the "**Company**"), and Carl Langren ("**Executive**") (collectively, the "**Parties**", each a "**Party**").

Whereas, the Company wishes to employ and/or continue to employ Executive and to assure itself of Executive's services on the terms set forth herein;

Whereas, Executive wishes to be employed by the Company on the terms set forth herein; and

Whereas, the Parties intend for this Agreement to set forth all of the terms and conditions of Executive's employment with the Company, and to supersede and replace all prior agreements, arrangements, representations or understandings between the Parties regarding Executive's employment with the Company.

AGREEMENT

Now, Therefore, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1. **Employment.** The Company will employ Executive and Executive shall serve the Company in the capacity of Chief Financial Officer ("CFO").

2. **Duties.** Executive shall render exclusive, full-time services to the Company. Executive shall report to the Chief Executive Officer ("CEO") in Executive's role. Executive shall perform services under this Agreement primarily at the Company's office in Austin, Texas, and from time to time at such other locations as may be necessary or as otherwise reasonably requested by the Company. Subject to the terms of this Agreement, Executive's responsibilities, working conditions and duties may be changed, expanded or eliminated at the sole discretion of the CEO. Executive shall devote Executive's best efforts and full business time, skill and attention to performance of Executive's duties on behalf of the Company; *provided, however*, that Executive may engage in civic and not-for-profit activities (*e.g.* charitable and industry association activities) as long as such activities do not materially interfere with Executive's obligations hereunder. During Executive's employment with the Company, Executive agrees not to engage in any business or for-profit activities outside the Company, including serving on any advisory boards or boards of directors of for-profit entities, except with the prior written approval of the CEO, which approval may be rescinded at any time in the CEO's sole discretion, provided that in the event of such rescission Executive shall be permitted reasonable time for orderly withdrawal from any board with respect to which such consent has been rescinded. By signing this Agreement, Executive represents that, to the best of Executive's knowledge, Executive is not subject to any other contract or duty that would interfere in any way with Executive's employment with the Company or performance of employment duties hereunder.

3. **Policies and Procedures.** Executive shall be subject to and will comply with the policies and procedures of the Company, as they may be modified, expanded or eliminated from time to time at the Company's sole discretion, except to the extent any such policy or procedure specifically conflicts with the express terms of this Agreement (in which case, this Agreement shall control).

4. **Base Salary.** For services rendered hereunder, Executive shall receive a base salary at the rate of $358,500 per year ("**Base Salary**"), paid periodically in accordance with ordinary Company payroll practices, subject to applicable payroll withholdings and deductions. Executive's Base Salary shall also be subject to annual reviews and periodic adjustment; provided that Executive's Base Salary may not be decreased without Executive's express written consent except in connection with an across-the-board reduction proportionally affecting all senior executives of the Company.

5. **Bonus.** Executive will be eligible to receive an annual performance bonus ("**Bonus**"), with a target level at 40% of Executive's Base Salary (the **"Bonus Target"**), with the annual amount of such Bonus to be determined in the sole discretion of the Company's Board of Directors (the "**Board**") or by its Compensation Committee (under authority delegated by the Board), based upon a review of both Executive's individual performance and the Company's performance (both of which may include, but are not limited to, achievement of certain milestones or performance objectives, if any, established by the Board or the Compensation Committee (the "**Bonus Plan**"))**.** The Board or the Compensation Committee, in their sole discretion, shall determine the extent to which Executive has achieved any performance targets or other terms and conditions applicable to the Bonus; the amount of the Bonus (if any); and whether and to what extent a Bonus may be paid with respect to any year during which Executive's employment terminates, subject to the terms and conditions of this Agreement. Bonuses are not earned until they are approved in writing by the Board or Compensation Committee. Any Bonuses earned shall be paid subject to applicable employment taxes, withholding and deductions. Except as otherwise expressly provided in this Agreement or in the Bonus Plan, Executive must remain continuously employed with the Company through the date a Bonus is approved in order to be eligible to receive such Bonus.

6. **Stock Options.** In consideration for entering into this Agreement, Executive shall be granted an option to purchase 100,000 shares of Company common stock (the "**Option**") subject to the vesting schedule and all other terms, conditions and limitations applicable to such Option as set forth in the Company's 2009 Equity Incentive Plan as it may be amended from time to time (the "**Equity Plan**") and in Stock Award Agreements (as defined in the Equity Plan) approved by the Board and entered into by Executive. Such grants to be awarded close of market the first of the month following date of promotion. Executive may receive additional equity grants from time to time, in the sole discretion of the Board or a designated committee thereof.

7. **Other Benefits.** While employed by the Company pursuant to this Agreement, Executive shall be entitled to the following benefits:

a. **Executive Benefits**. The Executive shall be entitled to all benefits to which other executive officers of the Company are entitled, on the same terms and conditions in effect from time to time, including, without limitation, participation in pension and profit sharing plans, the Company's 401(k) plan, group insurance policies and plans (including medical, health, vision, and disability insurance policies and plans, and the like) which may be maintained by the Company for the benefit of its executives. The Company reserves the right to alter, discontinue and/or amend its benefit plans and programs from time to time in its sole discretion.

b. **Expense Reimbursement.** The Executive shall receive, upon presentation of proper receipts and vouchers, reimbursement for direct and reasonable out-of-pocket expenses incurred in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policies and procedures in effect from time to time.

c. **Vacation.** Executive will accrue twenty-eight (28) days of paid vacation each full year, accrued in equal monthly increments, subject to Executive's continuing service. Unused vacation will carry over from year to year; provided, however, that Executive shall not be entitled to carry over more than a total of fifty-six (56) days of accrued vacation. Once that maximum vacation balance has been reached, Executive will cease to accrue any additional vacation time until Executive uses some vacation time and brings Executive's vacation balance below the applicable cap. Executive's vacation rights shall otherwise be governed by the Company's vacation policy and applicable law, as in effect from time to time.

8. **Confidential Information, Rights and Duties.**

a. **Proprietary Information.** Executive agrees to execute and abide by the Company's Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement (the "**Proprietary Information Agreement**"), attached hereto as **Exhibit A**.

b. **Exclusive Property**. Executive agrees that all Company-related business procured by the Executive, and all Company-related business opportunities and plans made known to Executive while employed by the Company, are and shall remain the permanent and exclusive property of the Company.

9. **Termination of Employment.**

a. **At-Will Status.** The Company and Executive understand and agree that this employment relationship is at-will. Accordingly, there are no promises or representations concerning the duration of Executive's employment relationship, and it may be terminated by either Executive or the Company at any time, with or without Cause or Good Reason (as defined herein), and with or without advance notice. Executive's at-will status cannot be altered except in an express written agreement signed by Executive and the Company with the specific approval of the Company's Board.

b. **Termination Due to Death or Disability.** Subject to applicable state or federal law, Executive's employment with the Company will automatically terminate upon Executive's death or Disability. For purposes of this Agreement, "**Disability**" means a physical or mental condition or disability which prevents Executive from performing Executive's job responsibilities for more than six (6) months in any twelve (12) month period, or for more than four (4) consecutive months.

c. **Resignation by Executive.** Executive may resign from the Company with or without Good Reason. The Company requests that Executive provide at least three (3) weeks' advance written notice of a termination without Good Reason to allow for an orderly transition. The Company may accelerate the date Executive's resignation is to become effective, in its sole discretion. In the event the company accelerates the resignation effective date, the Executive will be paid Base Salary severance through the originally tendered resignation date, provided that in no such event will Executive be entitled to receive more than three (3) months of Base Salary severance beyond the accelerated resignation date.

d. **Definition of Cause.** For purposes of this Agreement, "**Cause**" for the Company to terminate Executive shall mean: (i) Executive's incompetence or failure or refusal to perform satisfactorily any duties reasonably required of Executive by the Company (other than by reason of Disability), which failure continues for fifteen (15) days after Executive receives specific written notice to cure; (ii) Executive's conviction or plea of guilty or *nolo contendere* to any felony or to any other crime involving dishonesty or moral turpitude; (iii) any act or omission which constitutes a material breach of this Agreement, the Proprietary Information Agreement, the Company's policies, or Executive's fiduciary duty to the Company; (iv) any act or omission in connection with Executive's employment with the Company, which involves material personal dishonesty by Executive or demonstrates a willful or continuing disregard for the best interests of the Company; or (v) Executive's engaging in dishonorable or disruptive behavior, practices or acts which cause, or could be reasonably expected to cause, material harm or bring disrepute to the Company.

e. **Definition of Good Reason.** For purposes of this Agreement, "**Good Reason**" means the occurrence of any of the following without Executive's prior written consent: (i) a reduction in Executive's Base Salary or benefits that materially diminishes the aggregate value of Executive's compensation and benefits, unless a reduction is made in connection with an across-the-board reduction of all executives' base salaries and/or employee benefits by a percentage less than 20% and at least equal to the percentage by which Executive's Base Salary or employee benefits are reduced; (ii) in the event of such an across-the-board reduction and a subsequent across-the-board restoration of all or any portion of the reduced Base Salary or benefits, then a failure to restore Executive's Base Salary or benefits in at least a proportional manner; (iii) any reduction of Bonus Target level; (iv) a material reduction in Executive's duties, authority or responsibilities taken as a whole; or (v) a relocation of Executive's principal place of employment that would result in an increase in Executive's one-way commute by more than 30 miles. Notwithstanding the foregoing, "**Good Reason**" for Executive to resign shall not exist unless: (x) Executive provides the Company with specific written notice of the existence of the condition giving rise to Good Reason within ninety (90) days after its initial occurrence; (y) the Company fails to remedy such condition within thirty (30) days after its receipt of such written notice; and (z) Executive resigns within sixty (60) days after the cure period has lapsed.

f. **Final Pay upon Termination for Any Reason.** Except as otherwise provided by this Agreement and/or required by law, upon termination of Executive's employment for any reason, the Company's obligation to make payments hereunder shall cease, except that the Company shall pay all amounts due and payable for Executive's services through Executive's last day of employment (the "**Separation Date**"), including all accrued unpaid Base Salary and Bonus compensation earned through Separation Date, any benefits accrued prior to the Separation Date, all accrued but unused vacation as of the Separation Date, and any reimbursable business expenses incurred but not reimbursed as of the Separation Date.

g. **Severance Benefits upon a Covered Termination (No Change in Control).**

i. **Severance Benefits.** If Executive's employment is terminated by the Company without Cause or as a result of Executive's resignation for Good Reason or Executive's death or Disability (each a "**Covered Termination**"), Executive (or Executive's estate, as applicable) shall be eligible to receive the following severance benefits: (1) payment of an amount equal to twelve (12) months of Executive's Base Salary in effect immediately prior to the Separation Date, less applicable payroll tax withholdings and deductions (the "**Severance**") and (2) twelve (12) months of accelerated vesting of Executive's Option and all other equity awards granted under the Equity Plan (the **"Equity Awards")** (so that Executive becomes vested in the portion of the Equity Awards that would have become vested if Executive remained employed for 365 days after the Separation Date). In addition, the period following termination of employment during which the Equity Awards may be exercised shall be extended to twelve (12) months. Except for the foregoing accelerated vesting and extended exercise period benefit, all existing terms and conditions applicable to the Equity Awards shall remain in full force and effect. In addition, provided Executive timely elects to continue Executive's group health insurance coverage after the Separation Date pursuant to the federal COBRA law or, if applicable, state insurance laws (collectively, "**COBRA**"), and the terms of the governing health insurance policies, the Company will reimburse the monthly COBRA health insurance premiums (the "**COBRA Payments**") Executive pays to continue Executive's health insurance coverage (including dependent coverage) for twelve (12) months after the Separation Date or **until such earlier date as** Executive either becomes eligible for group health insurance coverage through a new employer or ceases to be eligible for COBRA coverage (the "**COBRA Payment Period**"). Executive must submit to the Company appropriate documentation of the foregoing health insurance payments, within sixty (60) days of making such payments, in order to be reimbursed. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Payments without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), at the end of each remaining month of the COBRA Payment Period, the Company shall pay Executive directly a taxable monthly amount which, after taxes, equals the COBRA Payment amount the Company would have otherwise paid to Executive (assuming a 35% tax rate). Executive agrees to promptly notify the Company in writing if Executive becomes eligible for group health insurance coverage through a new employer before the end of the specified reimbursement period. For sake of reference, all severance benefits provided in entire subsection 9(g)(i) shall be referred to collectively as the "**Severance Benefits.**"

ii. **Preconditions.** As a precondition to receiving any Severance Benefits, Executive must (1) remain in compliance with all continuing obligations Executive owes to the Company, including those set forth under Executive's Proprietary Information Agreement, and (2) within twenty-one (21) days after the Separation Date, Executive must sign and return to the Company, a separation agreement and release of claims in substantially the form attached hereto as **Exhibit B** (the "**Release**") and allow the Release to become fully-effective and non-revocable by its terms. The Severance will be paid in the form of continuing installments on the ordinary payroll schedule, and the Final Bonus will be paid in a lump sum following the Separation Date within ten (10) business days of the effective date of such Release.

10. **Change In Control Benefits.**

a. **Change in Control Termination.** If Executive's employment with the Company is terminated by the Company without Cause (but not due to Executive's death or Disability) or Executive resigns for Good Reason, and such termination or resignation occurs within one (1) month before, or within thirteen (13) months after a Change in Control (defined below) (each a "**CIC Termination**"), Executive shall be eligible to receive the following enhanced severance package (in lieu of the Severance Benefits described above): (i) payment of eighteen (18) months of Executive's Base Salary as in effect immediately prior to the Separation Date, less applicable withholdings and deductions; (ii) payment of a bonus in the amount equal to the most recently paid Bonus as described in Section 5 above multiplied by (1.5), less applicable withholdings and deductions (the payments under clauses (i) and (ii) referred to as the "**CIC Cash Severance**"); and (iii) accelerated vesting of Executive's Equity Awards so that Executive becomes one hundred percent (100%) vested in all such Equity Awards. In addition, the period following the Separation Date during which Executive's Equity Awards may be exercised shall be extended to twelve (12) months. Except for the noted accelerated vesting and extended exercise period benefits, all existing terms and conditions applicable to the Equity Awards shall remain in full force and effect. In addition, provided Executive timely elects to continue Executive's group health insurance coverage after the Separation Date pursuant to COBRA, and the terms of the governing health insurance policies, the Company will reimburse all monthly COBRA health insurance premiums the Executive pays to continue Executive's health insurance coverage (including dependent coverage) for eighteen (18) months after the Separation Date or **until such earlier date as** Executive either becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA coverage. The Change in Control severance benefits shall be paid subject to the same preconditions and on the same terms and conditions applicable to the Severance Benefits; provided, however, that the CIC Cash Severance shall be paid in the form of a lump sum within ten (10) business days of the Effective Date of the Release required under Section 9(g)(ii) (Preconditions).

b. **Definition of Change in Control.** For purposes of this Agreement, "**Change in Control**" has the definition set forth in the Equity Plan.

11. **Code Section 409A Compliance.** Notwithstanding anything set forth in this Agreement to the contrary, any payments and benefits provided pursuant to this Agreement which constitute "deferred compensation" within the meaning of the Treasury Regulations issued pursuant to Section 409A shall not commence until Executive has incurred a "separation from service" (as such term is defined in the Treasury Regulation Section 1.409A-1(h) ("**Separation From Service**"), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A.

For the avoidance of doubt, it is intended that the payments and benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9) and this Agreement will be construed to the greatest extent possible as consistent with those provisions. To the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A and incorporates by reference all required definitions and payment terms. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if the Company (or, if applicable, the successor entity thereto) determines that any payments upon Executive's Separation From Service set forth herein and/or under any other agreement with the Company constitute "deferred compensation" under Section 409A and Executive is, on Executive's Separation From Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of

the Code, then, solely, to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the payments upon Executive's Separation From Service shall be delayed until the earlier to occur of: (a) the date that is six months and one day after Executive's Separation From Service or (b) the date of Executive's death (such applicable date, the "**Specified Employee Initial Payment Date**"). On the Specified Employee Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the payments upon Executive's Separation From Service that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the severance benefits had not been so delayed pursuant to this section and (B) commence paying the balance of the severance benefits in accordance with the applicable payment schedules set forth in this Agreement.

None of the severance benefits under this Agreement will commence or otherwise be delivered prior to the effective date of the Release. Except to the minimum extent that payments must be delayed because Executive is a "specified employee" (as described above) or until the effectiveness of the Release, all amounts will be paid as soon as practicable in accordance with the Company's normal payroll practices and no interest will be due on any amounts so deferred.

12. **Better After Tax Provision.** If any payment or benefit that Executive will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment will be equal to the Reduced Amount. The "**Reduced Amount**" will be either (x) the largest portion of the 280G Payment that would result in no portion of the 280G Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the 280G Payment, whichever amount (*i.e.*, the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the 280G Payment may be subject to the Excise Tax. If a reduction in a 280G Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction will occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the 280G Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, will be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification will preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, 280G Payments that are contingent on future events (*e.g.*, being terminated without Cause), will be reduced (or eliminated) before 280G Payments that are not contingent on future events; and (C) as a third priority, 280G Payments that are "deferred compensation" within the meaning of Section 409A of the Code will be reduced (or eliminated) before 280G Payments that are not "deferred compensation" within the meaning of Section 409A of the Code.

If Section 280G of the Code is not applicable by law to Executive, the Company will determine whether any similar law in Executive's jurisdiction applies and should be taken into account.

The independent professional firm engaged by the Company for general tax audit purposes as of the day prior to the effective date of the Change in Control will make all determinations required to be made under this Section. If the firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company will appoint a nationally recognized independent professional firm to make the determinations required hereunder. The Company will bear all expenses with respect to the determinations by such firm required to be made hereunder. The Company will use commercially reasonable efforts to cause the firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting

documentation, to the Company and Executive within thirty (30) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive.

If Executive receives a 280G Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the 280G Payment is subject to the Excise Tax, Executive will promptly return to the Company a sufficient amount of the 280G Payment (after reduction pursuant to clause (x) of the first paragraph of this Section) so that no portion of the remaining 280G Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of the first paragraph of this Section, Executive will have no obligation to return any portion of the 280G Payment pursuant to the preceding sentence.

13. **Miscellaneous.**

a. **Taxes.** Executive shall be responsible for the payment of any taxes due on any and all compensation, stock option, or benefit provided by the Company pursuant to this Agreement which are not withheld by the Company. Executive agrees to indemnify and hold harmless the Company from any and all claims or penalties asserted against the Company arising from Executive's failure to pay taxes due on any compensation, stock option, or benefit provided by the Company pursuant to this Agreement. Executive expressly acknowledges that the Company has not made any representation about the tax consequences of any consideration provided by the Company to Executive pursuant to this Agreement.

b. **Modification/Waiver.** This Agreement may not be amended, modified, superseded, canceled, renewed or expanded, or any terms or covenants hereof waived, except by a writing executed by each of the Parties or, in the case of a waiver, by the Party waiving compliance. Failure of any Party at any time to require performance of any provision hereof shall in no manner affect his, her or its right at a later time to enforce such provision. No waiver by a Party of a breach of this Agreement shall be deemed to be or construed as a waiver of any other breach of any term or condition contained in the Agreement.

c. **Successors and Assigns.** This Agreement may be assigned by the Company to an affiliated entity or to any successor or assignee of the Company with or without Executive's consent. This Agreement shall not be assignable by Executive.

d. **Notices.** All notices to be given hereunder shall be in writing and shall be deemed to have been duly given on: the date personally or hand delivered; one (1) day after being sent by internationally-recognized overnight delivery courier; and three (3) days after being sent by certified mail, return receipt requested. Notices mailed to Executive shall be sent to Executive's last home address as reflected in the Company's personnel records. Executive promptly shall notify Company of any change in Executive's address. Notices to be issued to the Company shall be directed to the **CEO** and shall be mailed to the Company's headquarters.

e. **Dispute Resolution.** To aid in the rapid and economical resolution of any disputes that may arise in the course of Executive's employment relationship, the Parties agree that any and all disputes, claims, or demands arising from or relating to the terms of this Agreement (including but not limited to the Proprietary Information Agreement incorporated by reference herein), Executive's employment relationship with the Company, or the termination of that relationship (including statutory claims), shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration in Dallas, Texas conducted before a single neutral arbitrator by JAMS, Inc. ("JAMS") or its successor, under the then applicable JAMS Arbitration Rules and Procedures for Employment Disputes (available at http://www.jamsadr.com/rules-employment-arbitration/) and subject to JAMS' Policy on Employment Arbitration Minimum Standards of Procedural Fairness. **The Parties acknowledge that by agreeing to this arbitration procedure, they waive the right to resolve any such dispute, claim or demand through a trial by jury or judge or by administrative proceeding.** Executive will have the right to be represented by legal counsel at any arbitration proceeding, at Executive's expense. The arbitrator shall: (a) have authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based; and (c) have authority to, in the arbitrator's discretion, award recovery of attorneys' fees and costs to the prevailing party. The Company shall pay all JAMS' arbitration fees. Nothing in this Agreement is intended to prevent either Party from obtaining injunctive relief in a court of applicable jurisdiction to prevent irreparable harm pending the conclusion of any arbitration; or from enforcing any arbitration award in a court of applicable jurisdiction.

f. **Entire Agreement.** This Agreement, together with the Exhibits, sets forth the complete and exclusive agreement and understanding of the Parties with regard to the subject matter hereof, and supersedes any and all prior or contemporaneous agreements, promises, representations, or communications, written or oral, pertaining to the subject matter hereof. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement, and the invalid or unenforceable provision shall be modified to render it valid and enforceable consistent with the intent of the parties insofar as possible under applicable law. For purposes of construing this Agreement, any ambiguities shall not be construed against any party as the drafter. This Agreement may be executed in counterparts, which shall be deemed to be part of one original, and facsimile signatures shall be equivalent to original signatures. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Iowa, without regard to conflict of laws principles.

In Witness Whereof, the Parties have each duly executed this Agreement as of the date written above to indicate their understanding and acceptance of all of the above-stated terms and conditions.

NewLink Genetics Corporation

By: /s/ Charles J. Link, Jr. M.D.
Its: CEO

Executive

/s/ Carl Langren
Carl Langren

Exhibit A

EMPLOYEE PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

This Employee Proprietary Information, Inventions, Non-competition, and Non-solicitation Agreement (this "Agreement") is made in consideration for my employment or continued employment by NewLink Genetics Corporation or any of its subsidiaries (the "Company"), and the compensation now and hereafter paid to me. I hereby agree as follows:

1. Nondisclosure.

1.1 Recognition of Company's Rights; Nondisclosure. At all times during my employment and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information (defined below), except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such in writing. I will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to my work at Company and/or incorporates any Proprietary Information. I hereby assign to the Company any rights I may have or acquire in such Proprietary Information and recognize that all Proprietary Information shall be the sole property of the Company and its assigns.

1.2 Proprietary Information. The term "**Proprietary Information**" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company. By way of illustration but not limitation, "Proprietary Information" includes (a) tangible and intangible information relating to antibodies and other biological materials, cell lines, samples of assay components, media and/or cell lines and procedures and formulations for producing any such assay components, media and/or cell lines, formulations, products, processes, know-how, designs, formulas, methods, developmental or experimental work, clinical data, improvements, discoveries, plans for research, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers, and information regarding the skills and compensation of other employees of the Company; (b) trade secrets, inventions, mask works, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques (hereinafter collectively referred to as "Inventions"); (c) information regarding plans for research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and (d) information regarding the skills and compensation of other employees of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which is generally known in the trade or industry, which is not gained as result of a breach of this Agreement, and my own, skill, knowledge, know-how and experience to whatever extent and in whichever way I wish.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

1.4 No Improper Use of Information of Prior Employers and Others. During my employment by the Company I will not improperly use or disclose any confidential information or trade secrets, if any, of any third party, including but not limited to any former employer or any other person or entity to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished documents or any property belonging to any third party, including but not limited to any former employer or any other person or entity to whom I have an obligation of confidentiality unless consented to in writing by that third party. I will use in the

performance of my duties only information which is generally known and used by persons with training and experience comparable to my own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided, obtained, or developed by or for the Company.

2. Assignment of Inventions.

2.1 Proprietary Rights. The term "**Proprietary Rights"** shall mean all trade secret, patent, copyright, mask work and other intellectual property rights throughout the world.

2.2 Prior Inventions. Inventions, if any, patented or unpatented, which I made prior to the commencement of my employment with the Company are excluded from the scope of this Agreement. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Previous Inventions) attached hereto a complete list of all Inventions that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement (collectively referred to as "**Prior Inventions**"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in Exhibit A but am only to disclose a cursory name for each such invention, a listing of the party (ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on Exhibit A for such purpose. If no such disclosure is attached, I represent that there are no Prior Inventions. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

2.3 Assignment of Inventions. Subject to Sections 2.4, and 2.6, I hereby assign and agree to assign in the future (when any such Inventions or Proprietary Rights are first reduced to practice or first fixed in a tangible medium, as applicable) to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to this Section 2, are hereinafter referred to as "Company Inventions."

2.4 Nonassignable Inventions. I recognize that, in the event of a specifically applicable state law, regulation, rule, or public policy ("Specific Inventions Law"), this Agreement will not be deemed to require assignment of any invention which qualifies fully for protection under a Specific Inventions Law by virtue of the fact that any such invention was, for example, developed entirely on my own time without using the Company's equipment, supplies, facilities, or trade secrets and neither related to the Company's actual or demonstrably anticipated business, research or development, nor resulted from work performed by me for the Company. In the absence of a Specific Inventions Law, the preceding sentence will not apply.

2.5 Obligation to Keep Company Informed. During the period of my employment with the Company, I will promptly disclose to the Company fully and in writing all Inventions authored, conceived or reduced to practice by me, either alone or jointly with others; and all patent applications filed by me or on my behalf. At the time of each such disclosure, I will advise the Company in writing of any Inventions that I believe fully qualify for protection under the provisions of a Specific Inventions Law; and I will at that time provide to the Company in writing all evidence necessary to substantiate that belief. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to the Company pursuant to this Agreement relating to Inventions that qualify fully for protection under a Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.6 Government or Third Party. I also agree to assign all my right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States, as directed by the Company.

2.7 Works for Hire. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment at the Company and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

2.8 Enforcement of Proprietary Rights.

i. **Obligation to Assist.** I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of my employment, but the Company shall compensate me at a reasonable rate after my termination for time actually spent by me at the Company's request on such assistance.

ii. **Appointment of Attorney in Fact.** In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to the Company.

3. No Conflicts, Non-Solicitation, and Non-Interference. I acknowledge that during my employment I will have access to and knowledge of Proprietary Information. To protect the Company's Proprietary Information, I agree that during the period of my employment by the Company I will not, without the Company's express written consent, engage in any other employment or business activity directly related to the business in which the Company is now involved or becomes involved, nor will I engage in any other activities which conflict with my obligations to the Company or the interests of the Company. For the period of my employment by the Company and continuing until one year after my last day of employment with the Company, I will not: (a) directly or indirectly induce any employee of the Company to terminate or reduce his or her relationship with the Company; (b) solicit the business of any Client or Customer of the Company (other than on behalf of the Company) for any competitive purpose; or (c) induce any supplier, vendor, consultant or independent contractor of the Company to terminate or reduce his, her or its relationship with the Company. I agree that for purposes of this Agreement, a "**Client or Customer**" is any person or entity with whom or which, at any time during the two year period prior to my last day of employment with the Company, (i) I had direct dealings; (ii) an individual whom I supervised had direct dealings; or (iii) about whom or which I obtained confidential information. If any restriction set forth in this Section is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4. Covenant Not to Compete. I acknowledge that during my employment I will have access to and knowledge of Proprietary Information. To protect the Company's Proprietary Information, I agree that during my employment with the Company, whether full-time or part-time, and for a period of one year after my last day of employment with the Company, I will not directly or indirectly engage in (whether as an employee, consultant, proprietor, partner, director or otherwise), or have any ownership interest in, or participate in the financing, operation, management or control of, any person, entity, corporation or business that engages in a "Restricted Business" in a "Restricted Territory" (as defined below). It is agreed that ownership of (i) no more than one percent

(1%) of the outstanding voting stock of a publicly traded corporation, or (ii) any stock I presently own shall not constitute a violation of this provision.

4.1 Reasonable. I agree and acknowledge that the time limitation on the restrictions in this paragraph, combined with the geographic scope, is reasonable. I also acknowledge and agree that this paragraph is reasonably necessary for the protection of the Company's Proprietary Information as defined in paragraph 1.2 herein, that through my employment I shall receive adequate consideration for any loss of opportunity associated with the provisions herein, and that these provisions provide a reasonable way of protecting the Company's business value, some of which will be imparted to me in the ordinary course of my employment with the Company. If any restriction set forth in this paragraph 4 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4.2 As used herein, the terms:

(i) "**Restricted Business"** shall mean a business that is engaged in or is preparing to engage in any of the areas that the Company is actively pursuing, including but not limited to research, development and/or commercialization of (1) one or more products for the treatment of cancer or infectious disease based upon the Company's HyperAcute technology platform; (2) one or more products for the treatment of cancer based upon IDO, TDO or PTEN inhibitors; (3) vaccines against the Ebola virus; or (4) any other area of research, development, or commercialization drug or biologic candidate potentially likely which is intended to address the same enzymatic target (such as, for example, IDO) as any drug or biologic candidate that (i) is the subject area of research, development, or commercialization in which the Company or any subsidiary is engaged pursuant to a program which is being materially funded by the Company, a strategic partner of the Company, and/or a grant to the Company and (ii) as to which I participated in or was familiar with the details of such the research, development or commercialization during their time of my employment with Company or regarding which I possess Confidential Information. For purposes of the preceding sentence, the determination of the scope of the Company's business activities shall be made as of the date of termination of my employment.

(ii) "**Restricted Territory**" shall mean any state, county, or locality in the United States in which the Company conducts business and any other country, city, state, jurisdiction, or territory in which the Company does business or plans to do business.

5. Records. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and any other form that may be required by the Company) of all Proprietary Information developed by me and all Company Inventions made by me during the period of my employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

6. No Conflicting Obligation. I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by the Company, nor any other lawful obligation I have to any third party. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict herewith.

7. Return of Company Materials. When I leave the employ of the Company, or earlier if requested by the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas, documents, materials, and tangible or intangible property of the Company together with all copies thereof, and any other material containing or embodying any Company Inventions, Third Party Information or Proprietary Information of the Company without retaining any reproductions or embodiments thereof in whole or in part and in any medium. By way of example, such items include but are not limited to: Company files, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, information regarding potential business development partners, research and development information, sales and marketing information, operational

and personnel information, code, software, databases, computer-recorded information, and tangible property and equipment (including, but not limited to, computers, data storage devices, facsimile machines, mobile telephones, servers, credit cards, entry cards, identification badges and keys). In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice.

8. Legal and Equitable Remedies. Because my services are personal and unique and because I may have access to and become acquainted with the Proprietary Information of the Company, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement.

9. Notices. Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery or express delivery service (e.g., FedEx) to the appropriate address; upon delivery via facsimile; or if sent by certified or registered mail, three days after the date of mailing.

10. Notification of New Employer. In the event that I leave the employ of the Company, I hereby consent to the notification of my new employer of my rights and obligations under this Agreement.

11. General Provisions.

11.1 Governing Law; Consent to Personal Jurisdiction and Exclusive Forum. This Agreement will be governed by and construed according to the laws of the State of Iowa as such laws are applied to agreements entered into and to be performed entirely within Iowa between Iowa residents. I hereby expressly understand and consent that my employment is a transaction of business in the State of Iowa and constitutes the minimum contacts necessary to make me subject to the personal jurisdiction of the federal courts located in the State of Iowa, and the state courts located in the County of Story, Iowa, for any lawsuit filed against me by Company arising from or related to this Agreement. I agree and acknowledge that any controversy arising out of or relating to this Agreement or the breach thereof, or any claim or action to enforce this Agreement or portion thereof, or any controversy or claim requiring interpretation of this Agreement must be brought in a forum located within the State of Iowa. No such action may be brought in any forum outside the State of Iowa. Any action brought in contravention of this paragraph by one party is subject to dismissal at any time and at any stage of the proceedings by the other, and no action taken by the other in defending, counter claiming or appealing shall be construed as a waiver of this right to immediate dismissal. A party bringing an action in contravention of this paragraph shall be liable to the other party for the costs, expenses and attorney's fees incurred in successfully dismissing the action or successfully transferring the action to the federal courts located in the State of Iowa, or the state courts located in the County of Story, Iowa.

11.2 Severability. In case any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement; this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein; and such provision shall be deemed modified and enforceable, insofar as possible consistent with its original intent. By way of example, if, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

11.3 Successors and Assigns. This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns. My obligations under this Agreement are not assignable to any party.

11.4 Survival. The provisions of this Agreement shall survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee.

11.5 Employment. I agree and understand that my employment is at-will which means I or the Company each have the right to terminate my employment, with or without advanced notice and with or without cause. I further agree and understand that nothing in this Agreement shall confer any right with respect to continuation of employment by the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.

11.6 Waiver. To be valid, any waiver by me or the Company of any breach of this Agreement or right hereunder shall be specifically stated in writing, and shall not be a waiver of any preceding or succeeding breach unless so specifically stated. No waiver of any right under this Agreement and applicable law shall be construed as a waiver of any other right. Neither party shall be required to give notice to enforce strict adherence to all terms of this Agreement.

11.7 Entire Agreement. The obligations pursuant to this Agreement shall apply to any time during which I was previously, or am in the future, employed or engaged as a consultant by the Company, if no other agreement governs the subject matter thereof. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior communications and representations with respect to such subject matter. No modification of or amendment to this Agreement will be effective unless in writing and signed by the party to be charged. Any subsequent changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

EMPLOYEE PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

ACKNOWLEDGEMENT FORM

I acknowledge that I have been given a copy of the Employee Proprietary Information and Inventions Agreement, that I have read it, and that I understand its terms and procedures. Furthermore, I agree to abide by it and understand that if NewLink determines my conduct warrants it, I may be subject to discipline for breaches hereof, up to and including the immediate termination of my employment.

Carl Langren
Employee's Name (Please Print)

/s/ Carl Langren
Employee's Signature

7/26/2018
Date

Exhibit B

RELEASE

[To be signed on or within twenty-one (21) days after the Separation Date]

My employment with NewLink Genetics Corporation (the "**Company**") ended in all capacities on _____ (the "**Separation Date**"). I hereby confirm that I have been paid all compensation owed to me by the Company for all hours worked; I have received all the leave and leave benefits and protections for which I was eligible, pursuant to the Company's policies, applicable law, or otherwise; and I have not suffered any on-the-job injury or illness for which I have not already filed a workers' compensation claim.

If I choose to enter into this Release and allow it to become effective by its terms, the Company will provide me with certain severance benefits pursuant to the terms of the Employment Agreement between me and the Company dated _____, 2015 (the "**Agreement**"). I understand that I am not entitled to such severance benefits unless I return this fully-executed Release to the Company within twenty-one (21) days after the Separation Date, and allow this Release to become fully effective and non-revocable by its terms. (Capitalized terms used but not defined in this Release shall have the meaning ascribed to them in the Agreement.)

In exchange for the severance benefits to which I would not otherwise be entitled, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "**Released Parties**") from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or at the time that I sign this Release, including but not limited to claims arising from or in any way related to my employment with the Company or the termination of that employment (collectively, the "**Released Claims**"). By way of example, the Released claims include, but are not limited to: (1) all claims related to my compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (2) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (3) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (4) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("**ADEA**"), and Iowa and Texas state laws.

Notwithstanding the foregoing, the following are not included in the Released Claims (the "**Excluded Claims**"): (a) any claims for breach of the Agreement arising after the date on which I sign this Release; (2) claims for reimbursement of properly incurred business expenses prior to and through the Separation Date which are submitted to the Company for reimbursement within thirty (30) days after the Separation Date; (3) all rights I have in respect of the Equity Awards; (4) all claims for or rights to indemnification pursuant to the articles of incorporation and bylaws of the Company, any indemnification agreement to which I am a party, or under applicable law; and (5) all claims which cannot be waived as a matter of law. I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, or any other government agency, except that I acknowledge and agree that I am hereby waiving my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims that I have or might have against any of the parties released above that are not included in the Released Claims.

[IF EXECUTIVE IS 40 YEARS OF AGE OR OLDER] I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, and that the consideration given for this Release is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised, as required by the ADEA, that: (a) my waiver and release does not apply to any rights or claims that may arise after the date I sign this Release; (b) I have been advised that I have the right to consult with an attorney prior to executing this Release (although I may choose voluntarily not to do so); (c) I have been given twenty-one (21) days to consider this Release (although I may choose voluntarily to sign it earlier); (d) I have seven (7) days following my execution of this Release to revoke my acceptance of it (with such revocation to be delivered in writing to the Company within the 7-day revocation period); and (e) this Release will not be effective until the date upon which the revocation period has expired, which will be the eighth day after I sign it, provided I do not earlier revoke it ("**Effective Date**").

I further agree: (a) not to disparage the Company or any of the other Released Parties, in any manner likely to be harmful to its or their business, business reputation or personal reputation (although I may respond accurately and fully to any question, inquiry or request for information as required by legal process); (b) not to voluntarily (except in response to legal compulsion) assist any third party in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceedings against the Company, its affiliates, officers, directors, employees or agents; and (c) to reasonably cooperate with the Company by voluntarily (without legal compulsion) providing accurate and complete information, in connection with the Company's actual or contemplated defense, prosecution or investigation of any claims or demands by or against third parties, or other matters, arising from events, acts, or omissions that occurred during my employment with the Company. I hereby certify that I have returned, without retaining any reproductions (in whole or in part), all information, materials and other property of the Company, including but not limited to any such information, materials or property contained on any personally-owned electronic or other storage device (such as computer, cellular phone, PDA, tablet or the like).

This Release, together with the Agreement (including all Exhibits and documents incorporated therein by reference), constitutes the complete, final and exclusive embodiment of the entire agreement between me and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained in the Release or the Agreement, and it entirely supersedes any other such promises, warranties or representations, whether oral or written.

Reviewed, Understood and Agreed:

By: Date:

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made as of this 26th day of July, 2018, by and between NewLink Genetics Corporation (the "**Company**"), and Lori Lawley ("**Executive**") (collectively, the "**Parties**", each a "**Party**").

Whereas, the Company wishes to employ and/or continue to employ Executive and to assure itself of Executive's services on the terms set forth herein;

Whereas, Executive wishes to be employed by the Company on the terms set forth herein; and

Whereas, the Parties intend for this Agreement to set forth all of the terms and conditions of Executive's employment with the Company, and to supersede and replace all prior agreements, arrangements, representations or understandings between the Parties regarding Executive's employment with the Company.

AGREEMENT

Now, Therefore, in consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

1. **Employment.** The Company will employ Executive and Executive shall serve the Company in the capacity of Vice President - Finance and Corporate Controller ("VP Finance").

2. **Duties.** Executive shall render exclusive, full-time services to the Company. Executive shall report to the Chief Financial Officer ("CFO") in Executive's role. Executive shall perform services under this Agreement primarily at the Company's office in Austin, Texas, and from time to time at such other locations as may be necessary or as otherwise reasonably requested by the Company. Subject to the terms of this Agreement, Executive's responsibilities, working conditions and duties may be changed, expanded or eliminated at the sole discretion of the CFO. Executive shall devote Executive's best efforts and full business time, skill and attention to performance of Executive's duties on behalf of the Company; *provided, however*, that Executive may engage in civic and not-for-profit activities (*e.g.* charitable and industry association activities) as long as such activities do not materially interfere with Executive's obligations hereunder. During Executive's employment with the Company, Executive agrees not to engage in any business or for-profit activities outside the Company, including serving on any advisory boards or boards of directors of for-profit entities, except with the prior written approval of the CFO, which approval may be rescinded at any time in the CFO's sole discretion, provided that in the event of such rescission Executive shall be permitted reasonable time for orderly withdrawal from any board with respect to which such consent has been rescinded. By signing this Agreement, Executive represents that, to the best of Executive's knowledge, Executive is not subject to any other contract or duty that would interfere in any way with Executive's employment with the Company or performance of employment duties hereunder.

3. **Policies and Procedures.** Executive shall be subject to and will comply with the policies and procedures of the Company, as they may be modified, expanded or eliminated from time to time at the Company's sole discretion, except to the extent any such policy or procedure specifically conflicts with the express terms of this Agreement (in which case, this Agreement shall control).

4. **Base Salary.** For services rendered hereunder, Executive shall receive a base salary at the rate of $200,000 per year ("**Base Salary**"), paid periodically in accordance with ordinary Company payroll practices, subject to applicable payroll withholdings and deductions. Executive's Base Salary shall also be subject to annual reviews and periodic adjustment; provided that Executive's Base Salary may not be decreased without Executive's express written consent except in connection with an across-the-board reduction proportionally affecting all senior executives of the Company.

5. **Bonus.** Executive will be eligible to receive an annual performance bonus ("**Bonus**"), with a target level at 25% of Executive's Base Salary (the **"Bonus Target"**), with the annual amount of such Bonus to be determined in the sole discretion of the Company's Board of Directors (the "**Board**") or by its Compensation Committee (under authority delegated by the Board), based upon a review of both Executive's individual performance and the Company's performance (both of which may include, but are not limited to, achievement of certain milestones or performance objectives, if any, established by the Board or the Compensation Committee (the "**Bonus Plan**")**.** The Board or the Compensation Committee, in their sole discretion, shall determine the extent to which Executive has achieved any performance targets or other terms and conditions applicable to the Bonus; the amount of the Bonus (if any); and whether and to what extent a Bonus may be paid with respect to any year during which Executive's employment terminates, subject to the terms and conditions of this Agreement. Bonuses are not earned until they are approved in writing by the Board or Compensation Committee. Any Bonuses earned shall be paid subject to applicable employment taxes, withholding and deductions. Except as otherwise expressly provided in this Agreement or in the Bonus Plan, Executive must remain continuously employed with the Company through the date a Bonus is approved in order to be eligible to receive such Bonus.

6. **Stock Options.** In consideration for entering into this Agreement, Executive shall be granted an option to purchase 25,000 shares of Company common stock (the "**Option**"), subject to the vesting schedule and all other terms, conditions and limitations applicable to such Option as set forth in the Company's 2009 Equity Incentive Plan as it may be amended from time to time (the "**Equity Plan**") and in Stock Award Agreements (as defined in the Equity Plan) approved by the Board and entered into by Executive. Such grants to be awarded close of market the first of the month following date of promotion. Executive may receive additional equity grants from time to time, in the sole discretion of the Board or a designated committee thereof.

7. **Other Benefits.** While employed by the Company pursuant to this Agreement, Executive shall be entitled to the following benefits:

a. **Executive Benefits**. The Executive shall be entitled to all benefits to which other executive officers of the Company are entitled, on the same terms and conditions in effect from time to time, including, without limitation, participation in pension and profit sharing plans, the Company's 401(k) plan, group insurance policies and plans (including medical, health, vision, and disability insurance policies and plans, and the like) which may be maintained by the Company for the benefit of its executives. The Company reserves the right to alter, discontinue and/or amend its benefit plans and programs from time to time in its sole discretion.

b. **Expense Reimbursement.** The Executive shall receive, upon presentation of proper receipts and vouchers, reimbursement for direct and reasonable out-of-pocket expenses incurred in connection with the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policies and procedures in effect from time to time.

c. **Vacation.** Executive will accrue twenty-eight (28) days of paid vacation each full year, accrued in equal monthly increments, subject to Executive's continuing service. Unused vacation will carry over from year to year; provided, however, that Executive shall not be entitled to carry over more than a total of twenty-eight (28) days of accrued vacation. Once that maximum vacation balance has been reached, Executive will cease to accrue any additional vacation time until Executive uses some vacation time and brings Executive's vacation balance below the cap. Executive's vacation rights shall otherwise be governed by the Company's vacation policy and applicable law, as in effect from time to time.

8. **Confidential Information, Rights and Duties.**

a. **Proprietary Information.** Executive agrees to execute and abide by the Company's Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement (the "**Proprietary Information Agreement**"), attached hereto as **Exhibit A**.

b. **Exclusive Property**. Executive agrees that all Company-related business procured by the Executive, and all Company-related business opportunities and plans made known to Executive while employed by the Company, are and shall remain the permanent and exclusive property of the Company.

9. **Termination of Employment.**

a. **At-Will Status.** The Company and Executive understand and agree that this employment relationship is at-will. Accordingly, there are no promises or representations concerning the duration of Executive's employment relationship, and it may be terminated by either Executive or the Company at any time, with or without Cause or Good Reason (as defined herein), and with or without advance notice. Executive's at-will status cannot be altered except in an express written agreement signed by Executive and the Company with the specific approval of the Company's Board.

b. **Termination Due to Death or Disability.** Subject to applicable state or federal law, Executive's employment with the Company will automatically terminate upon Executive's death or Disability. For purposes of this Agreement, "**Disability**" means a physical or mental condition or disability which prevents Executive from performing Executive's job responsibilities for more than six (6) months in any twelve (12) month period, or for more than four (4) consecutive months.

c. **Resignation by Executive.** Executive may resign from the Company with or without Good Reason. The Company requests that Executive provide at least three (3) weeks' advance written notice of a termination without Good Reason to allow for an orderly transition. The Company may accelerate the date Executive's resignation is to become effective, in its sole discretion. In the event the company accelerates the resignation effective date, the Executive will be paid Base Salary severance through the originally tendered resignation date, provided that in no such event will Executive be entitled to receive more than three (3) months of Base Salary severance beyond the accelerated resignation date.

d. **Definition of Cause.** For purposes of this Agreement, "**Cause**" for the Company to terminate Executive shall mean: (i) Executive's incompetence or failure or refusal to perform satisfactorily any duties reasonably required of Executive by the Company (other than by reason of Disability), which failure continues for fifteen (15) days after Executive receives specific written notice to cure; (ii) Executive's conviction or plea of guilty or *nolo contendere* to any felony or to any other crime involving dishonesty or moral turpitude; (iii) any act or omission which constitutes a material breach of this Agreement, the Proprietary Information Agreement, the Company's policies, or Executive's fiduciary duty to the Company; (iv) any act or omission in connection with Executive's employment with the Company, which involves material personal dishonesty by Executive or demonstrates a willful or continuing disregard for the best interests of the Company; or (v) Executive's engaging in dishonorable or disruptive behavior, practices or acts which cause, or could be reasonably expected to cause, material harm or bring disrepute to the Company.

e. **Definition of Good Reason.** For purposes of this Agreement, "**Good Reason**" means the occurrence of any of the following without Executive's prior written consent: (i) a reduction in Executive's Base Salary or benefits that materially diminishes the aggregate value of Executive's compensation and benefits, unless a reduction is made in connection with an across-the-board reduction of all executives' base salaries and/or employee benefits by a percentage less than 20% and at least equal to the percentage by which Executive's Base Salary or employee benefits are reduced; (ii) in the event of such an across-the-board reduction and a subsequent across-the-board restoration of all or any portion of the reduced Base Salary or benefits, then a failure to restore Executive's Base Salary or benefits in at least a proportional manner; (iii) a material reduction in Executive's duties, authority or responsibilities taken as a whole; or (iv) a relocation of Executive's principal place of employment that would result in an increase in Executive's one-way commute by more than 30 miles. Notwithstanding the foregoing, "**Good Reason**" for Executive to resign shall not exist unless: (x) Executive provides the Company with specific written notice of the existence of the condition giving rise to Good Reason within ninety (90) days after its initial occurrence; (y) the Company fails to remedy such condition within thirty (30) days after its receipt of such written notice; and (z) Executive resigns within sixty (60) days after the cure period has lapsed.

f. **Final Pay upon Termination for Any Reason.** Except as otherwise provided by this Agreement and/or required by law, upon termination of Executive's employment for any reason, the Company's obligation to make payments hereunder shall cease, except that the Company shall pay all amounts due and payable for Executive's services through Executive's last day of employment (the "**Separation Date**"), including all accrued unpaid Base Salary and Bonus compensation earned through Separation Date, any benefits accrued prior to the Separation Date, all accrued but unused vacation as of the Separation Date, and any reimbursable business expenses incurred but not reimbursed as of the Separation Date.

g. **Severance Benefits upon a Covered Termination (No Change in Control).**

i. **Severance Benefits.** If Executive's employment is terminated by the Company without Cause or as a result of Executive's resignation for Good Reason or Executive's death or Disability (each a "**Covered Termination**"), Executive (or Executive's estate, as applicable) shall be eligible to receive the following severance benefits: (1) payment of an amount equal to six (6) months of Executive's Base Salary in effect immediately prior to the Separation Date, less applicable payroll tax withholdings and deductions (the "**Severance**") and (2) twelve (12) months of accelerated vesting of Executive's Option and all other equity awards granted under the Equity Plan (the **"Equity Awards")** (so that Executive becomes vested in the portion of the Equity Awards that would have become vested if Executive remained employed for 365 days after the Separation Date). Except for the foregoing accelerated vesting benefit, all existing terms and conditions applicable to the Equity Awards shall remain in full force and effect. In addition, provided Executive timely elects to continue Executive's group health insurance coverage after the Separation Date pursuant to the federal COBRA law or, if applicable, state insurance laws (collectively, "**COBRA**"), and the terms of the governing health insurance policies, the Company will reimburse the monthly COBRA health insurance premiums (the "**COBRA Payments**") Executive pays to continue Executive's health insurance coverage (including dependent coverage) for six (6) months after the Separation Date or **until such earlier date as** Executive either becomes eligible for group health insurance coverage through a new employer or ceases to be eligible for COBRA coverage (the "**COBRA Payment Period**"). Executive must submit to the Company appropriate documentation of the foregoing health insurance payments, within sixty (60) days of making such payments, in order to be reimbursed. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Payments without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), at the end of each remaining month of the COBRA Payment Period, the Company shall pay Executive directly a taxable monthly amount which, after taxes, equals the COBRA Payment amount the Company would have otherwise paid to Executive (assuming a 35% tax rate). Executive agrees to promptly notify the Company in writing if Executive becomes eligible for group health insurance coverage through a new employer before the end of the specified reimbursement period. For sake of reference, all severance benefits provided in entire subsection 9(g)(i) shall be referred to collectively as the "**Severance Benefits.**"

ii. **Preconditions.** As a precondition to receiving any Severance Benefits, Executive must (1) remain in compliance with all continuing obligations Executive owes to the Company, including those set forth under Executive's Proprietary Information Agreement, and (2) within twenty-one (21) days after the Separation Date, Executive must sign and return to the Company, a separation agreement and release of claims in substantially the form attached hereto as **Exhibit B** (the "**Release**") and allow the Release to become fully-effective and non-revocable by its terms. The Severance will be paid in the form of continuing installments on the ordinary payroll schedule, and the Final Bonus will be paid in a lump sum following the Separation Date within ten (10) business days of the effective date of such Release.

10. **Change In Control Benefits.**

a. **Change in Control Termination.** If Executive's employment with the Company is terminated by the Company without Cause (but not due to Executive's death or Disability) or Executive resigns for Good Reason, and such termination or resignation occurs within one (1) month before, or within thirteen (13) months after a Change in Control (defined below) (each a "**CIC Termination**"), Executive shall be eligible to receive the following enhanced severance package (in lieu of the Severance Benefits described above): (i) payment of twelve (12) months of Executive's Base Salary as in effect immediately prior to the Separation Date, less applicable withholdings and deductions; (ii) payment of a bonus in the amount equal to the most recently paid Bonus as described in Section 5 above, less applicable withholdings and deductions (the payments under clauses (i) and (ii) referred to as the "**CIC Cash Severance**"); and (iii) accelerated vesting of Executive's Equity Awards so that Executive becomes one hundred percent (100%) vested in all such Equity Awards. Except for the noted accelerated vesting benefits, all existing terms and conditions applicable to the Equity Awards shall remain in full force and effect. In addition, provided Executive timely elects to continue Executive's group health insurance coverage after the Separation Date pursuant to COBRA, and the terms of the governing health insurance policies, the Company will reimburse all monthly COBRA health insurance premiums the Executive pays to continue Executive's health insurance coverage (including dependent coverage) for twelve (12) months after the Separation Date or **until such earlier date as** Executive either becomes eligible for group health insurance coverage through a new employer or Executive ceases to be eligible for COBRA coverage. The Change in Control severance benefits shall be paid subject to the same preconditions and on the same terms and conditions applicable to the Severance Benefits; provided, however, that the CIC Cash Severance shall be paid in the form of a lump sum within ten (10) business days of the Effective Date of the Release required under Section 9(g)(ii) (Preconditions).

b. **Definition of Change in Control.** For purposes of this Agreement, "**Change in Control**" has the definition set forth in the Equity Plan.

11. **Code Section 409A Compliance.** Notwithstanding anything set forth in this Agreement to the contrary, any payments and benefits provided pursuant to this Agreement which constitute "deferred compensation" within the meaning of the Treasury Regulations issued pursuant to Section 409A shall not commence until Executive has incurred a "separation from service" (as such term is defined in the Treasury Regulation Section 1.409A-1(h) ("**Separation From Service**"), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A.

For the avoidance of doubt, it is intended that the payments and benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9) and this Agreement will be construed to the greatest extent possible as consistent with those provisions. To the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A and incorporates by reference all required definitions and payment terms. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A 2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if the Company (or, if applicable, the successor entity thereto) determines that any payments upon Executive's Separation From Service set forth herein and/or under any other agreement with the Company constitute "deferred compensation" under Section 409A and Executive is, on Executive's Separation From Service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely, to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the payments upon Executive's Separation From Service shall be delayed until the earlier to occur of: (a) the date that is six months and one day after Executive's Separation From Service or (b) the date of Executive's death (such applicable date, the "**Specified Employee Initial Payment Date**"). On the

Specified Employee Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall (A) pay to Executive a lump sum amount equal to the sum of the payments upon Executive's Separation From Service that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the severance benefits had not been so delayed pursuant to this section and (B) commence paying the balance of the severance benefits in accordance with the applicable payment schedules set forth in this Agreement.

None of the severance benefits under this Agreement will commence or otherwise be delivered prior to the effective date of the Release. Except to the minimum extent that payments must be delayed because Executive is a "specified employee" (as described above) or until the effectiveness of the Release, all amounts will be paid as soon as practicable in accordance with the Company's normal payroll practices and no interest will be due on any amounts so deferred.

12. **Better After Tax Provision.** If any payment or benefit that Executive will or may receive from the Company or otherwise (a "**280G Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then any such 280G Payment will be equal to the Reduced Amount. The "**Reduced Amount**" will be either (x) the largest portion of the 280G Payment that would result in no portion of the 280G Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the 280G Payment, whichever amount (*i.e.*, the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the 280G Payment may be subject to the Excise Tax. If a reduction in a 280G Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction will occur in the manner (the "**Reduction Method**") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the "**Pro Rata Reduction Method**").

Notwithstanding the foregoing, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the 280G Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, will be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification will preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second priority, 280G Payments that are contingent on future events (*e.g.*, being terminated without Cause), will be reduced (or eliminated) before 280G Payments that are not contingent on future events; and (C) as a third priority, 280G Payments that are "deferred compensation" within the meaning of Section 409A of the Code will be reduced (or eliminated) before 280G Payments that are not "deferred compensation" within the meaning of Section 409A of the Code.

If Section 280G of the Code is not applicable by law to Executive, the Company will determine whether any similar law in Executive's jurisdiction applies and should be taken into account.

The independent professional firm engaged by the Company for general tax audit purposes as of the day prior to the effective date of the Change in Control will make all determinations required to be made under this Section. If the firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company will appoint a nationally recognized independent professional firm to make the determinations required hereunder. The Company will bear all expenses with respect to the determinations by such firm required to be made hereunder. The Company will use commercially reasonable efforts to cause the firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to the Company and Executive within thirty (30) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by the Company or Executive) or such other time as requested by the Company or Executive.

If Executive receives a 280G Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section and the Internal Revenue Service determines thereafter that some portion of the 280G Payment is subject to the Excise Tax, Executive will promptly return to the Company a sufficient amount of the 280G Payment (after reduction pursuant to clause (x) of the first paragraph of this Section) so that no portion of the remaining 280G Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of the first paragraph of this Section, Executive will have no obligation to return any portion of the 280G Payment pursuant to the preceding sentence.

13. **Miscellaneous.**

a. **Taxes.** Executive shall be responsible for the payment of any taxes due on any and all compensation, stock option, or benefit provided by the Company pursuant to this Agreement which are not withheld by the Company. Executive agrees to indemnify and hold harmless the Company from any and all claims or penalties asserted against the Company arising from Executive's failure to pay taxes due on any compensation, stock option, or benefit provided by the Company pursuant to this Agreement. Executive expressly acknowledges that the Company has not made any representation about the tax consequences of any consideration provided by the Company to Executive pursuant to this Agreement.

b. **Modification/Waiver.** This Agreement may not be amended, modified, superseded, canceled, renewed or expanded, or any terms or covenants hereof waived, except by a writing executed by each of the Parties or, in the case of a waiver, by the Party waiving compliance. Failure of any Party at any time to require performance of any provision hereof shall in no manner affect his, her or its right at a later time to enforce such provision. No waiver by a Party of a breach of this Agreement shall be deemed to be or construed as a waiver of any other breach of any term or condition contained in the Agreement.

c. **Successors and Assigns.** This Agreement may be assigned by the Company to an affiliated entity or to any successor or assignee of the Company with or without Executive's consent. This Agreement shall not be assignable by Executive.

d. **Notices.** All notices to be given hereunder shall be in writing and shall be deemed to have been duly given on: the date personally or hand delivered; one (1) day after being sent by internationally-recognized overnight delivery courier; and three (3) days after being sent by certified mail, return receipt requested. Notices mailed to Executive shall be sent to Executive's last home address as reflected in the Company's personnel records. Executive promptly shall notify Company of any change in Executive's address. Notices to be issued to the Company shall be directed to the **CEO** and shall be mailed to the Company's headquarters.

e. **Dispute Resolution.** To aid in the rapid and economical resolution of any disputes that may arise in the course of Executive's employment relationship, the Parties agree that any and all disputes, claims, or demands arising from or relating to the terms of this Agreement (including but not limited to the Proprietary Information Agreement incorporated by reference herein), Executive's employment relationship with the Company, or the termination of that relationship (including statutory claims), shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration in Dallas, Texas conducted before a single neutral arbitrator by JAMS, Inc. ("JAMS") or its successor, under the then applicable JAMS Arbitration Rules and Procedures for Employment Disputes (available at http://www.jamsadr.com/rules-employment-arbitration/) and subject to JAMS' Policy on Employment Arbitration Minimum Standards of Procedural Fairness. **The Parties acknowledge that by agreeing to this arbitration procedure, they waive the right to resolve any such dispute, claim or demand through a trial by jury or judge or by administrative proceeding.** Executive will have the right to be represented by legal counsel at any arbitration proceeding, at Executive's expense. The arbitrator shall: (a) have authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based; and (c) have authority to, in the arbitrator's discretion, award recovery of attorneys' fees and costs to the prevailing party. The Company shall pay all JAMS' arbitration fees. Nothing in this Agreement is intended to prevent either Party from obtaining injunctive relief in a court of applicable jurisdiction to prevent irreparable harm pending the conclusion of any arbitration; or from enforcing any arbitration award in a court of applicable jurisdiction.

f. **Entire Agreement.** This Agreement, together with the Exhibits, sets forth the complete and exclusive agreement and understanding of the Parties with regard to the subject matter hereof, and supersedes any and all prior or contemporaneous agreements, promises, representations, or communications, written or oral, pertaining to the subject matter hereof. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement, and the invalid or unenforceable provision shall be modified to render it valid and enforceable consistent with the intent of the parties insofar as possible under applicable law. For purposes of construing this Agreement, any ambiguities shall not be construed against any party as the drafter. This Agreement may be executed in counterparts, which shall be deemed to be part of one original, and facsimile signatures shall be equivalent to original signatures. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the State of Iowa, without regard to conflict of laws principles.

In Witness Whereof, the Parties have each duly executed this Agreement as of the date written above to indicate their understanding and acceptance of all of the above-stated terms and conditions.

NewLink Genetics Corporation

By: /s/ Charles J. Link, Jr. M.D.
Its: CEO

Executive

/s/ Lori Lawley
Lori Lawley

Exhibit A

EMPLOYEE PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

This Employee Proprietary Information, Inventions, Non-competition, and Non-solicitation Agreement (this "Agreement") is made in consideration for my employment or continued employment by NewLink Genetics Corporation or any of its subsidiaries (the "Company"), and the compensation now and hereafter paid to me. I hereby agree as follows:

1. Nondisclosure.

1.1 Recognition of Company's Rights; Nondisclosure. At all times during my employment and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information (defined below), except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such in writing. I will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to my work at Company and/or incorporates any Proprietary Information. I hereby assign to the Company any rights I may have or acquire in such Proprietary Information and recognize that all Proprietary Information shall be the sole property of the Company and its assigns.

1.2 Proprietary Information. The term "**Proprietary Information**" shall mean any and all confidential and/or proprietary knowledge, data or information of the Company. By way of illustration but not limitation, "Proprietary Information" includes (a) tangible and intangible information relating to antibodies and other biological materials, cell lines, samples of assay components, media and/or cell lines and procedures and formulations for producing any such assay components, media and/or cell lines, formulations, products, processes, know-how, designs, formulas, methods, developmental or experimental work, clinical data, improvements, discoveries, plans for research, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers, and information regarding the skills and compensation of other employees of the Company; (b) trade secrets, inventions, mask works, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques (hereinafter collectively referred to as "Inventions"); (c) information regarding plans for research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and (d) information regarding the skills and compensation of other employees of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which is generally known in the trade or industry, which is not gained as result of a breach of this Agreement, and my own, skill, knowledge, know-how and experience to whatever extent and in whichever way I wish.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

1.4 No Improper Use of Information of Prior Employers and Others. During my employment by the Company I will not improperly use or disclose any confidential information or trade secrets, if any, of any third party, including but not limited to any former employer or any other person or entity to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished documents or any property belonging to any third party, including but not limited to any former employer or any other person or entity to whom I have an obligation of confidentiality unless consented to in writing by that third party. I will use in the

performance of my duties only information which is generally known and used by persons with training and experience comparable to my own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided, obtained, or developed by or for the Company.

2. Assignment of Inventions.

2.1 Proprietary Rights. The term "**Proprietary Rights"** shall mean all trade secret, patent, copyright, mask work and other intellectual property rights throughout the world.

2.2 Prior Inventions. Inventions, if any, patented or unpatented, which I made prior to the commencement of my employment with the Company are excluded from the scope of this Agreement. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Previous Inventions) attached hereto a complete list of all Inventions that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement (collectively referred to as "**Prior Inventions**"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in Exhibit A but am only to disclose a cursory name for each such invention, a listing of the party (ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on Exhibit A for such purpose. If no such disclosure is attached, I represent that there are no Prior Inventions. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

2.3 Assignment of Inventions. Subject to Sections 2.4, and 2.6, I hereby assign and agree to assign in the future (when any such Inventions or Proprietary Rights are first reduced to practice or first fixed in a tangible medium, as applicable) to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to this Section 2, are hereinafter referred to as "Company Inventions."

2.4 Nonassignable Inventions. I recognize that, in the event of a specifically applicable state law, regulation, rule, or public policy ("Specific Inventions Law"), this Agreement will not be deemed to require assignment of any invention which qualifies fully for protection under a Specific Inventions Law by virtue of the fact that any such invention was, for example, developed entirely on my own time without using the Company's equipment, supplies, facilities, or trade secrets and neither related to the Company's actual or demonstrably anticipated business, research or development, nor resulted from work performed by me for the Company. In the absence of a Specific Inventions Law, the preceding sentence will not apply.

2.5 Obligation to Keep Company Informed. During the period of my employment with the Company, I will promptly disclose to the Company fully and in writing all Inventions authored, conceived or reduced to practice by me, either alone or jointly with others; and all patent applications filed by me or on my behalf. At the time of each such disclosure, I will advise the Company in writing of any Inventions that I believe fully qualify for protection under the provisions of a Specific Inventions Law; and I will at that time provide to the Company in writing all evidence necessary to substantiate that belief. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to the Company pursuant to this Agreement relating to Inventions that qualify fully for protection under a Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.6 Government or Third Party. I also agree to assign all my right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States, as directed by the Company.

2.7 Works for Hire. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment at the Company and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

2.8 Enforcement of Proprietary Rights.

i. **Obligation to Assist.** I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of my employment, but the Company shall compensate me at a reasonable rate after my termination for time actually spent by me at the Company's request on such assistance.

ii. **Appointment of Attorney in Fact.** In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to the Company.

3. No Conflicts, Non-Solicitation, and Non-Interference. I acknowledge that during my employment I will have access to and knowledge of Proprietary Information. To protect the Company's Proprietary Information, I agree that during the period of my employment by the Company I will not, without the Company's express written consent, engage in any other employment or business activity directly related to the business in which the Company is now involved or becomes involved, nor will I engage in any other activities which conflict with my obligations to the Company or the interests of the Company. For the period of my employment by the Company and continuing until one year after my last day of employment with the Company, I will not: (a) directly or indirectly induce any employee of the Company to terminate or reduce his or her relationship with the Company; (b) solicit the business of any Client or Customer of the Company (other than on behalf of the Company) for any competitive purpose; or (c) induce any supplier, vendor, consultant or independent contractor of the Company to terminate or reduce his, her or its relationship with the Company. I agree that for purposes of this Agreement, a "**Client or Customer**" is any person or entity with whom or which, at any time during the two year period prior to my last day of employment with the Company, (i) I had direct dealings; (ii) an individual whom I supervised had direct dealings; or (iii) about whom or which I obtained confidential information. If any restriction set forth in this Section is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4. Covenant Not to Compete. I acknowledge that during my employment I will have access to and knowledge of Proprietary Information. To protect the Company's Proprietary Information, I agree that during my employment with the Company, whether full-time or part-time, and for a period of one year after my last day of employment with the Company, I will not directly or indirectly engage in (whether as an employee, consultant, proprietor, partner, director or otherwise), or have any ownership interest in, or participate in the financing, operation, management or control of, any person, entity, corporation or business that engages in a "Restricted Business" in a "Restricted Territory" (as defined below). It is agreed that ownership of (i) no more than one percent

(1%) of the outstanding voting stock of a publicly traded corporation, or (ii) any stock I presently own shall not constitute a violation of this provision.

4.1 Reasonable. I agree and acknowledge that the time limitation on the restrictions in this paragraph, combined with the geographic scope, is reasonable. I also acknowledge and agree that this paragraph is reasonably necessary for the protection of the Company's Proprietary Information as defined in paragraph 1.2 herein, that through my employment I shall receive adequate consideration for any loss of opportunity associated with the provisions herein, and that these provisions provide a reasonable way of protecting the Company's business value, some of which will be imparted to me in the ordinary course of my employment with the Company. If any restriction set forth in this paragraph 4 is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or geographic area as to which it may be enforceable.

4.2 As used herein, the terms:

(i) "**Restricted Business"** shall mean a business that is engaged in or is preparing to engage in any of the areas that the Company is actively pursuing, including but not limited to research, development and/or commercialization of (1) one or more products for the treatment of cancer or infectious disease based upon the Company's HyperAcute technology platform; (2) one or more products for the treatment of cancer based upon IDO, TDO or PTEN inhibitors; (3) vaccines against the Ebola virus; or (4) any other area of research, development, or commercialization drug or biologic candidate potentially likely which is intended to address the same enzymatic target (such as, for example, IDO) as any drug or biologic candidate that (i) is the subject area of research, development, or commercialization in which the Company or any subsidiary is engaged pursuant to a program which is being materially funded by the Company, a strategic partner of the Company, and/or a grant to the Company and (ii) as to which I participated in or was familiar with the details of such the research, development or commercialization during their time of my employment with Company or regarding which I possess Confidential Information. For purposes of the preceding sentence, the determination of the scope of the Company's business activities shall be made as of the date of termination of my employment.

(ii) "**Restricted Territory**" shall mean any state, county, or locality in the United States in which the Company conducts business and any other country, city, state, jurisdiction, or territory in which the Company does business or plans to do business.

5. Records. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and any other form that may be required by the Company) of all Proprietary Information developed by me and all Company Inventions made by me during the period of my employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

6. No Conflicting Obligation. I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by the Company, nor any other lawful obligation I have to any third party. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict herewith.

7. Return of Company Materials. When I leave the employ of the Company, or earlier if requested by the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas, documents, materials, and tangible or intangible property of the Company together with all copies thereof, and any other material containing or embodying any Company Inventions, Third Party Information or Proprietary Information of the Company without retaining any reproductions or embodiments thereof in whole or in part and in any medium. By way of example, such items include but are not limited to: Company files, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, information regarding potential business development partners, research and development information, sales and marketing information, operational

and personnel information, code, software, databases, computer-recorded information, and tangible property and equipment (including, but not limited to, computers, data storage devices, facsimile machines, mobile telephones, servers, credit cards, entry cards, identification badges and keys). In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice.

8. Legal and Equitable Remedies. Because my services are personal and unique and because I may have access to and become acquainted with the Proprietary Information of the Company, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement.

9. Notices. Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery or express delivery service (e.g., FedEx) to the appropriate address; upon delivery via facsimile; or if sent by certified or registered mail, three days after the date of mailing.

10. Notification of New Employer. In the event that I leave the employ of the Company, I hereby consent to the notification of my new employer of my rights and obligations under this Agreement.

11. General Provisions.

11.1 Governing Law; Consent to Personal Jurisdiction and Exclusive Forum. This Agreement will be governed by and construed according to the laws of the State of Iowa as such laws are applied to agreements entered into and to be performed entirely within Iowa between Iowa residents. I hereby expressly understand and consent that my employment is a transaction of business in the State of Iowa and constitutes the minimum contacts necessary to make me subject to the personal jurisdiction of the federal courts located in the State of Iowa, and the state courts located in the County of Story, Iowa, for any lawsuit filed against me by Company arising from or related to this Agreement. I agree and acknowledge that any controversy arising out of or relating to this Agreement or the breach thereof, or any claim or action to enforce this Agreement or portion thereof, or any controversy or claim requiring interpretation of this Agreement must be brought in a forum located within the State of Iowa. No such action may be brought in any forum outside the State of Iowa. Any action brought in contravention of this paragraph by one party is subject to dismissal at any time and at any stage of the proceedings by the other, and no action taken by the other in defending, counter claiming or appealing shall be construed as a waiver of this right to immediate dismissal. A party bringing an action in contravention of this paragraph shall be liable to the other party for the costs, expenses and attorney's fees incurred in successfully dismissing the action or successfully transferring the action to the federal courts located in the State of Iowa, or the state courts located in the County of Story, Iowa.

11.2 Severability. In case any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement; this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein; and such provision shall be deemed modified and enforceable, insofar as possible consistent with its original intent. By way of example, if, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

11.3 Successors and Assigns. This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns. My obligations under this Agreement are not assignable to any party.

11.4 Survival. The provisions of this Agreement shall survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee.

11.5 Employment. I agree and understand that my employment is at-will which means I or the Company each have the right to terminate my employment, with or without advanced notice and with or without cause. I further agree and understand that nothing in this Agreement shall confer any right with respect to continuation of employment by the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.

11.6 Waiver. To be valid, any waiver by me or the Company of any breach of this Agreement or right hereunder shall be specifically stated in writing, and shall not be a waiver of any preceding or succeeding breach unless so specifically stated. No waiver of any right under this Agreement and applicable law shall be construed as a waiver of any other right. Neither party shall be required to give notice to enforce strict adherence to all terms of this Agreement.

11.7 Entire Agreement. The obligations pursuant to this Agreement shall apply to any time during which I was previously, or am in the future, employed or engaged as a consultant by the Company, if no other agreement governs the subject matter thereof. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior communications and representations with respect to such subject matter. No modification of or amendment to this Agreement will be effective unless in writing and signed by the party to be charged. Any subsequent changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

EMPLOYEE PROPRIETARY INFORMATION AND INVENTIONS AGREEMENT

ACKNOWLEDGEMENT FORM

I acknowledge that I have been given a copy of the Employee Proprietary Information and Inventions Agreement, that I have read it, and that I understand its terms and procedures. Furthermore, I agree to abide by it and understand that if NewLink determines my conduct warrants it, I may be subject to discipline for breaches hereof, up to and including the immediate termination of my employment.

Lori Lawley
Employee's Name (Please Print)

/s/ Lori Lawley
Employee's Signature

July 26, 2018
Date

Exhibit B

RELEASE

[To be signed on or within twenty-one (21) days after the Separation Date]

My employment with NewLink Genetics Corporation (the "**Company**") ended in all capacities on _____ (the "**Separation Date**"). I hereby confirm that I have been paid all compensation owed to me by the Company for all hours worked; I have received all the leave and leave benefits and protections for which I was eligible, pursuant to the Company's policies, applicable law, or otherwise; and I have not suffered any on-the-job injury or illness for which I have not already filed a workers' compensation claim.

If I choose to enter into this Release and allow it to become effective by its terms, the Company will provide me with certain severance benefits pursuant to the terms of the Employment Agreement between me and the Company dated _____, 2015 (the "**Agreement**"). I understand that I am not entitled to such severance benefits unless I return this fully-executed Release to the Company within twenty-one (21) days after the Separation Date, and allow this Release to become fully effective and non-revocable by its terms. (Capitalized terms used but not defined in this Release shall have the meaning ascribed to them in the Agreement.)

In exchange for the severance benefits to which I would not otherwise be entitled, I hereby generally and completely release the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "**Released Parties**") from any and all claims, liabilities and obligations, both known and unknown, arising from or in any way related to events, acts, conduct, or omissions occurring prior to or at the time that I sign this Release, including but not limited to claims arising from or in any way related to my employment with the Company or the termination of that employment (collectively, the "**Released Claims**"). By way of example, the Released claims include, but are not limited to: (1) all claims related to my compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (2) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (3) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (4) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("**ADEA**"), and Iowa and Texas state laws.

Notwithstanding the foregoing, the following are not included in the Released Claims (the "**Excluded Claims**"): (a) any claims for breach of the Agreement arising after the date on which I sign this Release; (2) claims for reimbursement of properly incurred business expenses prior to and through the Separation Date which are submitted to the Company for reimbursement within thirty (30) days after the Separation Date; (3) all rights I have in respect of the Equity Awards; (4) all claims for or rights to indemnification pursuant to the articles of incorporation and bylaws of the Company, any indemnification agreement to which I am a party, or under applicable law; and (5) all claims which cannot be waived as a matter of law. I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, or any other government agency, except that I acknowledge and agree that I am hereby waiving my right to any monetary benefits in connection with any such claim, charge or proceeding. I hereby represent and warrant that, other than the Excluded Claims, I am not aware of any claims that I have or might have against any of the parties released above that are not included in the Released Claims.

[IF EXECUTIVE IS 40 YEARS OF AGE OR OLDER] I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, and that the consideration given for this Release is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised, as required by the ADEA, that: (a) my waiver and release does not apply to any rights or claims that may arise after the date I sign this Release; (b) I have been advised that I have the right to consult with an attorney prior to executing this Release (although I may choose voluntarily not to do so); (c) I have been given twenty-one (21) days to consider this Release (although I may choose voluntarily to sign it earlier); (d) I have seven (7) days following my execution of this Release to revoke my acceptance of it (with such revocation to be delivered in writing to the Company within the 7-day revocation period); and (e) this Release will not be effective until the date upon which the revocation period has expired, which will be the eighth day after I sign it, provided I do not earlier revoke it ("**Effective Date**").

I further agree: (a) not to disparage the Company or any of the other Released Parties, in any manner likely to be harmful to its or their business, business reputation or personal reputation (although I may respond accurately and fully to any question, inquiry or request for information as required by legal process); (b) not to voluntarily (except in response to legal compulsion) assist any third party in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceedings against the Company, its affiliates, officers, directors, employees or agents; and (c) to reasonably cooperate with the Company by voluntarily (without legal compulsion) providing accurate and complete information, in connection with the Company's actual or contemplated defense, prosecution or investigation of any claims or demands by or against third parties, or other matters, arising from events, acts, or omissions that occurred during my employment with the Company. I hereby certify that I have returned, without retaining any reproductions (in whole or in part), all information, materials and other property of the Company, including but not limited to any such information, materials or property contained on any personally-owned electronic or other storage device (such as computer, cellular phone, PDA, tablet or the like).

This Release, together with the Agreement (including all Exhibits and documents incorporated therein by reference), constitutes the complete, final and exclusive embodiment of the entire agreement between me and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained in the Release or the Agreement, and it entirely supersedes any other such promises, warranties or representations, whether oral or written.

Reviewed, Understood and Agreed:

By: Date:

EXHIBIT 31.1

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

1. 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: November 2, 2018

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

EXHIBIT 31.2

CERTIFICATION

I, Carl W. Langren, 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

1. 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: November 2, 2018

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Charles J. Link, Jr., Chief Executive Officer of NewLink Genetics Corporation (the "Company"), and Carl W. Langren, Chief Financial Officer and Secretary of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, 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: November 2, 2018

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

By: /s/ Carl W. Langren
Carl W. Langren
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.