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 March 31, 2019.
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 ☒

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	NLNK	The Nasdaq Stock Market

As of May 6, 2019, there were 37,276,102 shares of the registrant’s Common Stock, par value $0.01 per share, outstanding.

NewLink Genetics Corporation

FORM 10-Q

Table of Contents

PART I

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 113,184	$ 120,738
Prepaid expenses and other current assets	4,447	5,536
Income tax receivable	341	339
Other receivables	305	459
Total current assets	118,277	127,072
Property and equipment, net	3,520	3,727
Right-of-use asset	7,334	—
Income tax receivable	140	140
Total non-current assets	10,994	3,867
Total assets	$ 129,271	$ 130,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 896	$ 555
Accrued expenses	6,950	8,139
Current portion of deferred rent	—	92
Current portion of lease liability	963	—
Current portion of notes payable	63	61
Total current liabilities	8,872	8,847
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable	27	43
Lease liability	7,353	—
Deferred rent	—	906
Total long-term liabilities	13,380	6,949
Total liabilities	$ 22,252	$ 15,796
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2019 and December 31, 2018; issued and outstanding shares — 0 at March 31, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2019 and December 31, 2018; issued 37,387,876 and 37,343,547 at March 31, 2019 and December 31, 2018, respectively, and outstanding 37,276,102 and 37,251,220 at March 31, 2019 and December 31, 2018, respectively	373	373
Additional paid-in capital	409,143	407,199
Treasury stock, at cost: 111,774 and 92,327 shares at March 31, 2019 and December 31, 2018, respectively	(1,449)	(1,417)
Accumulated deficit	(301,048)	(291,012)
Total stockholders' equity	$ 107,019	$ 115,143
Total liabilities and stockholders' equity	$ 129,271	$ 130,939

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating revenues:		
Grant revenue	$ —	$ 9,384
Licensing and collaboration revenue	106	516
Total operating revenues	106	9,900
Operating expenses:		
Research and development	5,203	20,314
General and administrative	5,567	8,292
Total operating expenses	10,770	28,606
Loss from operations	(10,664)	(18,706)
Other income and expense:		
Miscellaneous income	5	24
Interest income	624	385
Interest expense	(1)	(13)
Other income, net	628	396
Net loss before taxes	(10,036)	(18,310)
Income tax benefit	—	—
Net loss	$ (10,036)	$ (18,310)
Basic and diluted loss per share	$ (0.27)	$ (0.49)
Basic and diluted average shares outstanding	37,275,459	37,155,082

See accompanying notes to condensed consolidated financial statements.

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

	Three Month Period ended March 31, 2019					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2018	37,251,220	$ 373	$ 407,199	$ (1,417)	$ (291,012)	$ 115,143
Share-based compensation	—	—	1,944	—	—	1,944
Restricted stock vested	44,329	—	—	—	—	—
Repurchase of common stock	(19,447)	—	—	(32)	—	(32)
Net loss	—	—	—	—	(10,036)	(10,036)
Balance at March 31, 2019	37,276,102	$ 373	$ 409,143	$ (1,449)	$ (301,048)	$ 107,019

	Three Month Period ended March 31, 2018					
	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	—	—	4,820	—	—	4,820
Restricted stock vested	84,262	1	105	—	—	106
Repurchase of common stock	(28,720)	—	—	(261)	—	(261)
Cumulative effect of accounting change	—	—	—	—	42	42
Net loss	—	—	—	—	(18,310)	(18,310)
Balance at March 31, 2018	37,165,098	$ 373	$ 394,711	$ (1,403)	$ (255,727)	$ 137,954

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Cash Flows From Operating Activities		
Net loss	$ (10,036)	$ (18,310)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,944	4,820
Depreciation and amortization	208	334
Gain on sale of fixed assets	(5)	(25)
Amortization of right-of-use assets	(16)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,088	146
Other receivables	154	330
Accounts payable and accrued expenses	(848)	(1,907)
Income taxes receivable	(2)	17
Unearned revenue	—	(56)
Deferred rent	—	(25)
Net cash used in operating activities	(7,513)	(14,676)
Cash Flows From Investing Activities		
Proceeds on sale of equipment	5	83
Net cash provided by investing activities	5	83
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	—	106
Repurchase of common stock	(32)	(261)
Principal payments on notes payable	(14)	(69)
Net cash used in financing activities	(46)	(224)
Net decrease in cash and cash equivalents	(7,554)	(14,817)
Cash and cash equivalents at beginning of period	120,738	158,708
Cash and cash equivalents at end of period	$ 113,184	$ 143,891
Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 1	$ 3
Cash paid (refunds received) for taxes, net	$ 2	$ (17)

See accompanying notes to condensed consolidated financial statements.

NewLink Genetics Corporation
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 to develop 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 March 31, 2019 and for the three months ended March 31, 2019 have been prepared assuming the Company will continue as a going concern. The Company 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.

The Company's cash and cash equivalents as of March 31, 2019 are expected to be adequate to satisfy the Company's liquidity requirements through 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, 2018, 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 was $90,000 and $104,000 as of March 31, 2019 and December 31, 2018, 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 $7.2 million and $7.0 million as of March 31, 2019 and December 31, 2018, respectively. 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 Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02 (Topic 842), Leases, to improve financial reporting for leasing transactions. The Company adopted the standard on January 1, 2019 using the modified retrospective method, as required, applying the new standard to all leases existing as of the date of initial application. The Company has elected that the date of the initial application will be the effective date, or January 1, 2019. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. The Company elected the 'package of practical expedients', which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect to apply the use-of-hindsight or the practical expedient pertaining to land easements; as the latter is not applicable to the Company.

Upon adoption of the standard, the Company recorded a lease liability of $8.5 million and a right of use asset of $7.5 million associated with these leases. Included in the right-of-use asset are lease incentives that were previously recorded as deferred rent liability of $1.0 million as of December 31, 2018 on the consolidated balance sheet. There was no material impact to the consolidated statement of operations.

4. Revenues

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. Prior to transferring the government contracts over to Merck Sharp & Dohme Corp. (Merck) in June 2018, the Company received payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services (HHS). These agreements provided 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 were recognized over time and measured using the input method. The Company used labor costs and subcontractor fees as inputs to measure progress towards satisfying its performance obligations under these agreements. Under this method, the Company recognized revenue generally in the period during which the related costs were incurred, in an amount that reflected the consideration the Company expected to be entitled to in exchange for those goods or services transferred to the government entities due to the government entities' control over the research and development activities.

The grants and contracts with government entities were fully transferred to Merck as of June 2018. Accordingly, during the first quarter of 2019, the Company recognized no grant revenue. The Company had $32,000 and $309,000 of receivables relating to the government contracts on the balance sheet as of March 31, 2019 and December 31, 2018. The Company had $38,000 and $54,000 of accrued expenses for subcontractor fees incurred under the government contracts as of March 31, 2019 and December 31, 2018, respectively.

5. License and Research Collaboration Agreement

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement (the Merck Agreement) with Merck, to develop, manufacture and commercialize rVSV-ZEBOV-GP, an Ebola vaccine the Company licensed from the Public Health Agency of Canada (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 is expected to 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 (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, the U.S. BioMedical Advanced Research and Development Authority (BARDA), and the Defense Threat Reduction Agency (DTRA) 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.

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. For the three months ended March 31, 2019, the Company recognized revenues under the Merck Agreement of $106,000 for work the Company is performing as a subcontractor of Merck under the government contracts that were transferred to Merck. For the three months ended March 31, 2018, the Company recognized license and collaboration revenue under the Merck Agreement of $460,000 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 (the 2000 Plan), and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the 2009 Plan). Following the approval of the 2009 Plan, no additional stock awards were granted under the 2000 Plan. Shares that remained available for issuance pursuant to the exercise of options or issuance or settlement of stock awards under the 2000 Plan became available for issuance pursuant to the 2009 Plan and all shares that would have otherwise returned to the 2000 Plan became available for issuance pursuant to 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 March 31, 2019, there were 12,400,653 shares of common stock authorized for the 2009 Plan and 1,926,633 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	714,285
January 1, 2012	823,649
January 1, 2013	839,407
January 1, 2014	1,062,920
January 1, 2015	1,119,233
January 1, 2016	1,152,565
January 1, 2017	1,166,546
January 1, 2018	1,484,382
January 1, 2019	1,490,048

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 2012 through 2019 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 (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 March 31, 2019, no shares remain available for issuance under the Directors' Plan.

2010 Employee Stock Purchase Plan

Under the terms of the Company’s 2010 Employee Stock Purchase Plan (the 2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of March 31, 2019, 53,509 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three months ended March 31, 2019 and 2018 was $1.9 million and $4.8 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 March 31, 2019, the total compensation cost related to nonvested option awards not yet recognized was $8.4 million and the weighted-average period over which it is expected to be recognized is 2.6 years.

Stock Options and Performance Stock Options

The following table summarizes the stock option activity, including options with market and performance conditions, for the three months ended March 31, 2019:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	7,979,644	$ 11.86	4.5
Options granted	1,436,675	1.80	
Options exercised	—	—	
Options forfeited	(25,000)	8.56	
Options expired	(61,060)	21.30	
Outstanding at end of period	9,330,259	$ 10.26	5.2
Options exercisable at end of period	6,451,246	$ 12.48	3.3

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 three months ended March 31, 2019:

Risk-free interest rate	2.6% to 2.7%
Expected dividend yield	—%
Expected volatility	77.6% to 79.5%
Expected term (in years)	4.0 to 7.7
Weighted-average grant-date fair value per share	$1.28

No options were exercised during the three months ended March 31, 2019. The fair value of awards vested during the three months ended March 31, 2019 was $2.1 million.

During the three months ended March 31, 2019, the Company's Board of Directors approved and granted 650,000 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 $1.24. The equity awards vest upon the achievement of certain performance conditions. Certain performance conditions relating to the equity awards granted in 2017 were met during the three months ended March 31, 2019 and 79,849 shares vested.

Restricted Stock and Performance Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the planning 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 March 31, 2019 and changes during the three months ended March 31, 2019 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	68,585	$ 37.75
Granted	—	—
Vested	(44,329)	39.02
Forfeited/cancelled	—	—
Unvested at end of period	24,256	$ 35.43

As of March 31, 2019, the total remaining unrecognized compensation cost related to restricted stock was approximately $673,000 and is expected to be recognized over a weighted-average period of 0.7 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. Leases

The Company has certain facility leases with non-cancellable terms ranging between one and three years, with certain renewal options.

The Company records lease liabilities based on the present value of lease payments over the lease term using an incremental borrowing rate to discount its lease liabilities, as the rate implicit in the lease is typically not readily determinable. To compute the present value of the lease liability, the Company used a weighted-average discount rate of 5%. Certain lease agreements include renewal options that are under the Company's control. The Company includes optional renewal periods in the lease term only when it is reasonably certain that the Company will exercise its option. The weighted-average remaining lease term as of March 31, 2019 is 11.7 years.

The Company does not separate lease components from non-lease components. Variable lease payments include payments to lessors for taxes, maintenance, insurance and other operating costs as well as payments that are adjusted based on an index or rate. The Company's lease agreements do not contain any residual value guarantees or restrictive covenants.

Future minimum lease payments under the non-cancellable operating leases (with initial or remaining lease terms in excess of one year) as of March 31, 2019 are as follows (in thousands):

For the Year Ended December 31:		
2019	$	823
2020		1,004
2021		923
2022		906
2023		909
Thereafter		6,570
Total future minimum lease payments	$	11,135
Less: imputed interest		(2,819)
Total	$	8,316

The following table summarizes the aggregate undiscounted non-cancelable future minimum lease payments for operating leases under the prior lease standard as of December 31, 2018 (in thousands):

For the Year Ended December 31:		
2019	$	1,105
2020		1,004
2021		923
2022		906
2023		909
Thereafter		6,570
Total	$	11,417

8. Income Taxes

For the three months ended March 31, 2019 and 2018, the Company recorded no income tax benefit. The income tax benefit for the three months ended March 31, 2019 and 2018 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to a full valuation allowance recorded against anticipated net operating loss carryforwards.

The Company has a noncurrent income tax receivable as of March 31, 2019 for $140,000 which was recorded as an income tax benefit in 2017 and is for the receipt of alternative minimum tax (AMT) credit carryovers. The Tax Cuts and Jobs Act of 2017 (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 March 31, 2019 and December 31, 2018, 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 March 31, 2019 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.

9. 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):

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

	Three Months Ended March 31,	
	2019	2018
Loss attributable to common stockholders	$ (10,036)	$ (18,310)
Basic and diluted weighted-average shares outstanding	37,275,459	37,155,082
Basic and diluted loss per share	$ (0.27)	$ (0.49)

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 March 31, 2019, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 9,330,259 and 24,256, respectively. As of March 31, 2018, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 8,369,519 and 100,719, respectively.

10. 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, is 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 advance its clinical development programs. No restructuring charges were recorded during the three months ended March 31, 2019.

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, 2018	$ 649	$ 649
Expensed	—	—
Cash Payments	214	214
Balance as of March 31, 2019	$ 435	$ 435

11. 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 (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (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, (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company’s investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. 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 do 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. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The court set a schedule in which appellants' (plaintiffs) brief is due May 17, 2019, appellees' (defendants) brief is due June 21, 2019, and appellants may file a reply no later than July 8, 2019. 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 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 (collectively, the Morrow Defendants), captioned Morrow v. Link., et al., Case 1:17-cv-03039 (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 (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 has until March 15, 2019 (30 days after dismissal of the Securities Action with prejudice) to file an amended derivative complaint or rest upon the current derivative complaint. By further agreement of the parties, dated March 15, 2019, the Ely Action will continue to be stayed pending the outcome of the appeal in the Securities Action. If the Securities Action continues to be dismissed in its entirety following its appeal plaintiff in the Ely Action has agreed to withdraw or dismiss the action, with prejudice. 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, 2018. 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 (IDO) pathway, which is one of the key pathways for cancer immune escape. These 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. We also have an additional small molecule product candidate, NLG207 (formerly CRLX101), which is a nanoparticle-drug conjugate (NDC) consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase 1 inhibitor.

Based on early clinical data from our Phase 1/2 clinical trials, our clinical program is focused on targeted indications with great unmet need where indoximod, NLG802, and NLG207 have produced encouraging early data. We plan to advance our core clinical programs and expect to present additional data supporting these research efforts in 2019. We anticipate presenting updated Phase 1 data for indoximod in both front-line diffuse intrinsic pontine glioma (DIPG) and our indoximod prodrug, NLG802.

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 (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 IDO 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 breakdown product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Preclinical and, increasingly, clinical data suggest 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 primarily focused on the IDO pathway. Our small-molecule IDO pathway inhibitor product candidates currently 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 acts as a tryptophan mimetic, thereby signaling the activation of antitumor T-cells by the activation of mammalian target of rapamycin (mTOR), acts directly on T-cells, and modulates aryl hydrocarbon receptor (AhR)-mediated effects.

We have observed an encouraging safety profile for our IDO pathway inhibitors. They are also 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-programmed cell death ligand-1 (PD-L1), or anti-cytotoxic T-lymphocyte antigen 4 (CLTA4). Clinical data suggest an increase in clinical activity without adding significant toxicity.

Indoximod

Indoximod, our lead IDO pathway inhibitor, is currently in clinical development in combination with other cancer therapeutics for patients with DIPG, acute myeloid leukemia, and melanoma. We believe there may be additional opportunities to apply indoximod to a broader set of cancer indications. More than 900 patients have been treated with indoximod to date and it has generally been well-tolerated, including in combination with PD-1 checkpoint inhibitors, various chemotherapy agents, radiation, and a cancer vaccine.

A tablet formulation of indoximod hydrochloride has been developed for adult patients and a sprinkle formulation is being developed for pediatric indications. We plan to use our new tablet formulation of indoximod in future clinical trials.

Two U.S. patents covering both the salt and prodrug formulations of indoximod were issued in the U.S. on August 15, 2017 and February 19, 2019 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 levels currently achievable by direct oral administration of indoximod. We filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (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, Inc. (Genentech). In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech (the Genentech Agreement). The Genentech Agreement provided for the development and commercialization of NLG919. On December 6, 2017, the Genentech Agreement with respect to NLG919 was terminated. As part of the partial termination, worldwide rights to NLG919 reverted to us and Genentech granted us a license under certain of Genentech’s intellectual property to develop and commercialize NLG919. We continue to explore the potential for further development and licensing opportunities but do not have an active program for the drug product candidate as of March 31, 2019.

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 (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 was terminated in its entirety on November 6, 2018 and we received control of the intellectual property portfolio related to the newly discovered TDO inhibitors, IDO inhibitors and dual IDO/TDO inhibitors.

Additional Product Candidates

NLG207

NLG207 is a NDC consisting of a cyclodextrin-based polymer backbone linked to camptothecin, a topoisomerase-1, or top-1, inhibitor. Because the vasculature in tumors is more permeable than normal tissue, we believe NDCs have the potential to enhance drug delivery to tumors by enabling gradual payload release inside cancer cells to augment antitumor activity while reducing off-target toxicity. NLG207 has been studied in more than 400 patients as monotherapy or in combination with other anticancer agents for patients with solid tumors.

A Phase 2 trial evaluating NLG207 plus paclitaxel for patients with recurrent ovarian, fallopian tube or primary peritoneal cancer was completed in collaboration with the Gynecological Oncology Group and the results of the trial were presented at the annual meeting for the American Association for Cancer Research on April 2, 2019.

Ebola Vaccine Candidate

In November 2014, we entered into the Merck Agreement 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 (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 by the FDA and successfully commercialized by Merck. 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 (BARDA), and the Defense Threat Reduction Agency (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.

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. No restructuring charges were recorded during the three months ended March 31, 2019 relating to this reorganization.

Corporate Information

Founded in 1999, our executive offices and manufacturing facilities are located in the Iowa State University Research Park in Ames, Iowa. We have approximately 26,616 square feet, comprising executive office space and space dedicated to manufacturing, testing and product storage, leased with the Iowa State University Research Park Corporation. We have additional executive and administrative space in Austin, Texas and clinical, regulatory and executive offices in Wayne, Pennsylvania.

We incurred a net loss of $10.0 million for the three months ended March 31, 2019. 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, 2018 discusses our most critical accounting policies. Since December 31, 2018, there have been no material changes in the critical accounting policies discussed in our 2018 Annual Report.

Recent Accounting Pronouncements

We adopted ASC Topic 842 on January 1, 2019 and have disclosed the impact adoption had on our condensed consolidated financial statements within Note 3 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 March 31, 2019 and 2018

Revenues. Revenues for the three months ended March 31, 2019 were $106,000, a decrease of $9.8 million from $9.9 million for the same period in 2018. The decrease in revenue was due to a decrease in grant revenue of $9.4 million, primarily attributable to a decrease in billings under the government grant contracts which were fully transferred to Merck in June 2018, and a decrease of $410,000 in licensing revenue, attributable to lower billings to Merck. We recognized licensing revenue during the three months ended March 31, 2019 for work we performed as a subcontractor of Merck.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2019 were $5.2 million, a decrease of $15.1 million from $20.3 million for the same period in 2018. The decrease was primarily due to reductions of $9.9 million in contract research and manufacturing spend, $2.2 million in personnel-related and stock compensation expense, $2.1 million in clinical trial expense, $500,000 in supplies and licensing, and $400,000 in legal and consulting expense.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2019 were $5.6 million, a decrease of $2.7 million from $8.3 million for the same period in 2018. The decrease was due primarily to reductions of $2.1 million in personnel-related and stock compensation expense, $605,000 in legal and consulting expense, offset by an increase of $72,000 in supplies and travel expense.

Income Tax Benefit. We did not record any income tax benefit for the three months ended March 31, 2019 and 2018, respectively.

Net Loss. The net loss for the three months ended March 31, 2019 was $10.0 million compared to a net loss of $18.3 million for the same period in 2018. The basic and diluted weighted-average common shares outstanding for the three months ended March 31, 2019 were 37,275,459, resulting in a basic and diluted loss per share of $0.27. For the three months ended March 31, 2018, the basic and diluted weighted-average common shares outstanding were 37,155,082, resulting in basic and diluted loss per share of $0.49.

Liquidity and Capital Resources

As of March 31, 2019, we had cash and cash equivalents of $113.2 million. We have historically funded our operations principally through the private placement of equity securities, public offerings of common stock, and license and milestone payments received under our collaboration agreements. We believe that our cash and cash equivalents on hand will be sufficient to fund our operations through 2021.

With the exception of fiscal year 2014, 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 our product candidates, 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 through 2021.

Cash Flows

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

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (7,513)	$ (14,676)
Net cash provided by investing activities	5	83
Net cash used in financing activities	(46)	(224)
Net decrease in cash and equivalents	$ (7,554)	$ (14,817)

For the three months ended March 31, 2019 and 2018, we used cash of $7.5 million and $14.7 million, respectively, for our operating activities. The decrease in cash used in operating activities was primarily due to the decrease in research and development activity and changes in working capital for the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

For the three months ended March 31, 2019 and 2018, our investing activities provided cash of $5,000 and $83,000, respectively. The cash provided by investing activities during the three months ended March 31, 2019 was due to proceeds received from sales of property and equipment of $5,000. The cash provided by investing activities during the three months ended March 31, 2018 was due to proceeds received from sales of property and equipment of $83,000.

For the three months ended March 31, 2019 and 2018, our financing activities used cash of $46,000 and $224,000, respectively. The cash used in financing activities during the three months ended March 31, 2019 was due to the net payments made on long-term obligations and notes payable of $14,000 and repurchases of common stock of $32,000. The cash provided by financing activities during the three months ended March 31, 2018 was primarily due to the issuance of common stock for net proceeds of $106,000, offset by net payments on long-term obligations and notes payable of $69,000, and repurchase of common stock of $261,000.

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 March 31, 2019 and December 31, 2018, we had cash and cash equivalents of $113.2 million and $120.7 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 bears 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

The Company’s principal executive officer and principal financial officer have concluded, based on an evaluation of the Company’s disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) or 15d-15(e)) as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15 that, as of March 31, 2019, the Company’s disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

In connection with the evaluation of the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2019, which is required under the Securities Exchange Act of 1934 by paragraph (d) of Exchange Rules 13a-15 or 15d-15 (as defined in paragraph (f) of Rule 13a-15), management determined that there was no change that materially affected or is reasonably likely to materially affect internal control over financial reporting.

PART II. OTHER INFORMATION

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 (the Court), captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545 (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 (collectively, the Defendants). The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. The Defendants filed a motion to dismiss the amended complaint on July 14, 2017. 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 do 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. On February 13, 2019, the Court dismissed the second amended complaint for failure to state a claim, with prejudice, and closed the case. On March 14, 2019, lead plaintiffs filed a notice of appeal. The court set a schedule in which appellants' (plaintiffs) brief is due May 17, 2019, appellees' (defendants) brief is due June 21, 2019, and appellants may file a reply no later than July 8, 2019. The Company intends to continue defending the Securities Action vigorously.

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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 commercialize indoximod successfully, 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 IND 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 (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 the prevention of, and may later be developed for the 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 (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 (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, NLG207, 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 supplied indoximod 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, NLG207, 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 most 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, NLG207, 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, NLG207, 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 the 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 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 the 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 biologics license application (BLA) and new drug application (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. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label, although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications. Companies may also share truthful and not misleading information that is otherwise consistent with the labeling. 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 the 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 payor 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 payors are increasingly challenging the price and cost-effectiveness of medical products and services.

Significant uncertainty exists as to the reimbursement status of newly approved 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 (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 (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 (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 (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 the United States Office of Management and Budget 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 (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 (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." 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. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Although the Texas U.S. District Court Judge, as well as the presidential administration and CMS have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 (the Right to Try Act) was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND 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 (the Directive), and the European Union's General Data Protection Regulation (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 our 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, 2017 and 2018 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 $10.0 million for the three months ended March 31, 2019 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. We are obligated to make aggregate payments ranging from approximately $250,000 to $2.8 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, 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 months ended March 31, 2019 we have no income tax benefit or expense. 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 comprehensive tax reform bill of 2017 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 (the Code) and included, among other things, significant changes to corporate taxation, including a reduction of the corporate income 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 for net operating losses arising in taxable years beginning after December 31, 2017 and elimination of net operating loss carrybacks for net operating losses arising in taxable years beginning after December 31, 2017, 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 did not have a material impact on our business. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act 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 the Tax Act 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 affected 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, NLG207, 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 was terminating the Genentech Agreement with respect to NLG919 and gave 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 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 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 (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 (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 March 31, 2019, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 40.7% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after March 31, 2019. 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 (the Exchange Act), the Sarbanes-Oxley Act of 2002 (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 Code.

Sections 382 and 383 of the 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 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		License Agreement dated September 13, 2005 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.46	X
10.1.1		Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.47	X
10.1.2		Amendment to License Agreement dated April 27, 2006 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.48	X
10.1.3		Amendment to License Agreement dated February 13, 2007 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	S-1/A	11/8/2011	10.49	X
10.1.4		Amendment dated March 28, 2006 to the License Agreement by and between the Company and Georgia Regents Research Institute, Inc., formerly known as Medical College of Georgia Research Institute	10-Q	11/10/2014	10.3	X
10.1.5		Amendment to License Agreement dated July 10, 2014 by and between the Registrant and Medical College of Georgia Research Institute, Inc.	10-Q	11/10/2014	10.4	X
31.1		Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2		Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1	#	Section 1350 Certification				X
101.INS	‡	XBRL Instance Document - 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

"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: May 8, 2019

By: /s/ Carl W. Langren
Carl W. Langren
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: May 8, 2019

Exhibit 10.1

THIS LICENSE AGREEMENT is made and entered into as of this 13 day of September, 2005, by and between the MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE, INC., a nonprofit Georgia corporation with offices located in the Medical College of Georgia, 1462 Laney Walker Blvd, Room CA-2125, Augusta, Georgia 30912-4810 (hereinafter referred to as "MCGRI") and NEWLINK GENETICS CORPORATION, a Delaware corporation with corporate headquarters located at 2901 South Loop Drive Suite 3900, Ames, Iowa 50010 (hereinafter referred to as "LICENSEE").

WITNESSETH

WHEREAS, the Medical College of Georgia Research Institute (MCGRI) is the assignee of all right, title, and interest in inventions developed by employees of The Medical College of Georgia (MCG) and is responsible for the protection and commercial development of such inventions; and

WHEREAS, David Munn, Andrew Mellor and Stephen Peiper, during the course of his/her/their employment by the Medical College of Georgia (MCG), developed certain inventions (MCG Case #'s 007-98, 007-98-Div 1, 007-98-Div 2, 011-98, 011-02, 003-03, 009-03) as more fully defined in Exhibit A; and

WHEREAS, MCGRI wants to have the inventions further developed and made available in commerce for use by the public; and

WHEREAS, LICENSEE represents that it has the necessary expertise and resources to fully develop and commercialize the inventions; and

WHEREAS, LICENSEE wishes to obtain certain rights to pursue the development and commercialization of the inventions; and

WHEREAS, MCGRI wishes to grant LICENSEE such rights in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, for and in consideration of the mutual covenants and the premises herein contained, the parties, intending to be legally bound, hereby agree as follows.

ARTICLE 1. DEFINITIONS

The following terms as used herein shall have the following meaning:

1.1 "Affiliate" shall mean, with respect to Licensee, a person, corporation or other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with Licensee. For the purposes of this definition, "control" means the direct or indirect ownership of at least twenty percent (20%) of the outstanding voting securities of the controlled entity.

1.2 “Agreement” or “License Agreement” shall mean this Agreement, including all Exhibits attached to this Agreement.

1.3 “Field of Use” means any and all medical applications, including without limitation, prevention, diagnostics, and therapy, including action as an adjuvant.

1.4 “Improvement” shall mean any invention, that is conceived or reduced to practice in the laboratory of any Inventor (or of his/their collaborators), that relates to an invention claimed in or covered by the Licensed Patents or which is a modification of the inventions claimed in or covered by the Licensed Patents.

1.5 “Indemnitees” shall mean MCGRI, MCGRI’s officers and directors, MCG, MCG’s employees, and the Inventors, and their heirs, executors, administrators, and legal representatives.

1.6 “Inventors” shall mean David Munn, Andrew Mellor and/or Stephen Peiper, as applicable with respect to each Licensed Patent.

1.7 “License Agreement Year” shall mean the period from July 1 through June 30 of each year during the term of this Agreement.

1.8 “Licensed Patents” shall mean the patent applications and patents identified in EXHIBIT A hereof and any patent applications controlled by MCGRI that claim Improvements, together with all divisionals, continuations, continuations-in-part (to the extent directed to the subject matter specifically described in such patent applications and patents), reissues, and foreign counterparts of such applications or patents.

1.9 “Licensed Product(s)” shall mean any process, service, or product, the manufacture, use, or sale of which is covered by a Valid Claim or incorporates or uses any Licensed Technology.

1.10 “Licensed Technology” shall mean all information and materials proprietary to MCGRI, including designs, technical information, know how, knowledge, data, specifications, test results and other information relating to the Licensed Patents and disclosed by MCGRI to LICENSEE on the date of this Agreement or during the term hereof on an exclusive, confidential basis and which is not available from another source.

1.11 “Licensed Territory” means worldwide.

1.12 “Net Selling Price” of Licensed Products shall mean the gross revenues received by Licensee or its Affiliate from a purchaser of a Licensed Product that is not a Sublicensee of Licensee or its Affiliate (unless such Sublicensee is the end user of such Licensed Product, in which case the amount received therefore shall be deemed to be the amount that would be billed to a third party end user in an arm’s-length transaction) including, if applicable, the value of all properties and services received in consideration of a Sale of Licensed Products, less the following items, as allocable to such Licensed Product (if not previously deducted from the amount invoiced): (i) trade discounts, credits or allowances; (ii) credits or allowances additionally granted upon returns, rejections or recalls; (iii) freight, shipping and insurance charges; (iv) taxes, duties or other governmental tariffs (other than income taxes); and (v) government mandated rebates. Where a Sale is deemed consummated by a gift, use, or other disposition

of Licensed Products for other than a selling price stated in cash, the term “Net Selling Price” shall mean the average gross selling price billed by LICENSEE in consideration of the Sale of comparable Licensed Products during the three (3) month period immediately preceding such Sale, without reduction of any kind; provided, however, that transfers and use of Licensed Products in clinical trials or for promotional or sampling purposes shall not be considered in determining Net Selling Price.

If the Licensed Products are Sold in combination with one or more other products or services which are not Licensed Products, Net Selling Price for such combination products will be calculated on a country-by-country basis by multiplying actual net selling price of such combination products by the fraction A/(A+B) where A is the average invoice price during the period of the Licensed Product when Sold separately, and B is the average invoice price of any other product(s) or services in the combination when Sold separately by Licensee. If the products or services in the combination that are not Licensed Products are not Sold separately by Licensee, Net Selling Price shall be calculated by multiplying actual net selling price of such combination products by the fraction A/C where A is the average invoice price of the Licensed Product when Sold separately and C is the average invoice price of the combination product. If neither the Licensed Product nor the combination product is Sold separately by Licensee, then Net Selling Price for royalty purposes hereunder for Sales of such combination product shall be determined by multiplying the Net Selling Price (calculated in the manner described above) of such combination product by a fraction, determined by mutual agreement of the parties, that reflects the relative contribution in value that the Licensed Product included in the combination product makes to the total value of such combination product.

1.13 “Sale” or “Sold” shall mean the sale, transfer, exchange, or other disposition of Licensed Products for value to a party other than LICENSEE or its Affiliate. Sales of Licensed Products shall be deemed consummated upon the first to occur of: (a) receipt of payment from the purchaser; or (b) if otherwise transferred, exchanged, or disposed of for consideration other than cash whether by gift or otherwise when such transfer, exchange, gift, or other disposition occurs.

1.14 “MCG” shall mean The Medical College of Georgia.

1.15 “Sublicensee” shall mean a third party to whom Licensee or its Affiliate has granted a sublicense under the Licensed patents to make, use, sell, offer to sell or import Licensed Products, beyond the mere right to purchase Licensed Product from Licensee or its Affiliate.

1.16 “Valid Claim” shall mean a claim included among the issued and unexpired Licensed Patents so long as such claim shall not have been irrevocably abandoned or held invalid in an unappealable decision of a court or other authority of competent jurisdiction.

ARTICLE 2. GRANT OF LICENSE

2.1 License. MCGRI hereby grants LICENSEE and its Affiliates an exclusive right and license under the Licensed Patents and Licensed Technology to make, use, import, offer to sell and sell Licensed Products for the Field of Use in the Licensed Territory during the term of this Agreement.

2.2 Sublicensing. Licensee and its Affiliates may sublicense to one or more third parties the rights granted under this Agreement, subject to the prior approval of MCGRI, not to be unreasonably withheld or delayed. If this Agreement is terminated for any reason, any sublicenses granted shall remain in full force and effect and be directly enforceable by MCGRI.

2.3 Retained License. MCGRI retains on behalf of itself, MCG, the Inventors and any academic research collaborators, a royalty-free right and license to make and use Licensed Products and to practice Licensed Technology for research and educational purposes only.

2.4 No Implied License. The license and right granted in this Agreement shall not be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology not specifically identified in this Agreement as Licensed Patents or Licensed Technology.

2.5 Government Rights. The Licensed Patents, Licensed Technology, or portions thereof may have been developed with financial or other assistance through grants or contracts funded by the United States government. LICENSEE acknowledges that in accordance with Public Law 96-517 and other statutes, regulations, and Executive Orders as now exist or may be amended or enacted, the United States government has certain rights in the Licensed Patents and Licensed Technology. LICENSEE shall take all action necessary to enable MCGRI to satisfy its obligations under any federal law relating to the Licensed Patents or Licensed Technology.

2.6 Publications. MCGRI shall have the right to publish any information included in the Licensed Patents subject to the provisions of this § 2.5 and Article 9. MCGRI shall provide to Licensee copies of any proposed presentation or publication or abstract disclosing information included in the Licensed Patents prior to the submission of such documents. Proposed publications and abstracts shall be supplied at least thirty (30) days in advance of submission to a journal, editor, or third party. Licensee may request reasonable changes and/or deletions be made in any proposed publication in order to protect the Licensed Patents and Licensee's confidential information. MCGRI (or any of its personnel) will consider such changes but retains the sole right to determine whether such changes or deletions will be made; but MCGRI agrees that it will honor (and will cause its personnel to honor) Licensee's reasonable requests to remove any confidential information of Licensee included in any such public disclosure. MCGRI agrees to delay such proposed public disclosure for up to ninety (90) days and to use commercially reasonable efforts to cooperate in the filing of a U.S. patent application as provided in Article 7 covering such subject matter prior to public disclosure.

ARTICLE 3. DILIGENCE AND COMMERCIALIZATION

3.1 Licensee agrees to invest $500,000 toward the further development of Licensed Products in the field of cancer therapy within eighteen (18) months after the execution date of the Agreement. If Licensee fails to make the required investment, and does not remedy that failure within sixty (60) days after written notice to Licensee, MCGRI, as its sole and exclusive remedy for such failure, may convert Licensee's right and license in the Field of Use for oncology to non-exclusive.

3.2 Licensee agrees to provide to MCGRI an annual report regarding Licensee's (or its Affiliates' or Sublicensees') progress in other areas of Licensed Product development (outside of cancer). MCGRI has the sole right to determine if non-cancer areas are receiving due diligence in product development in accordance with standards common to the industry, taking into account efficacy, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Licensed Products, the likelihood of regulatory approval given the regulatory structure involved, the profitability of the Licensed Product and alternative products and all other relevant factors. If Licensee has not met basic product development milestones, and does not remedy that failure within sixty (60) days after written notice from MCGRI, Licensee's right and license in that area of the Field of Use (specifically, infectious disease or diagnostics) will revert from exclusive to non-exclusive for that specific application.

ARTICLE 4. CONSIDERATION FOR LICENSE

4.1 License Fee. As partial consideration for the license granted to LICENSEE under this Agreement, LICENSEE shall pay MCGRI a license fee of One Hundred Sixty Thousand Dollars ($160,000). The license fee shall be paid in two equal installments of Eighty Thousand Dollars ($80,000). The first such installment shall be due within sixty (60) days of signing this Agreement, and the second installment shall be due no later than six (6) months after the first payment. Licensee will issue to MCGRI twenty five thousand (25,000) shares of Licensee's common stock (such number of shares to be adjusted for any stock dividends, combinations, splits, recapitalizations, and the like occurring after the effective date of the Agreement), subject to execution and delivery by MCGRI of a stock subscription agreement in the form of Exhibit B hereto. In regard to Improvement technologies created after the signing of this Agreement, if LICENSEE elects to include such technologies under this Agreement, there shall be a one-time License Fee of Twenty Thousand Dollars ($20,000) per technology, upon payment of which the new technology is considered part of this Agreement.

4.2 Sublicensing Fee. Licensee shall pay MCGRI twenty five percent (25%) of any fees or payments or remuneration paid to LICENSEE by a Sublicensee in relation to this License and for rights to all or part of the Licensed Patents (other than research funding, equity, loans or patent costs or fee reimbursements). Such percentage shall decrease five percent (5%) for each year of the term of this Agreement in which Licensee expends at least Two Hundred Fifty Thousand Dollars ($250,000) towards the development of Licensed Products, but not to go below a floor of ten percent (10%).

4.3 Royalties. As partial consideration for the license granted to LICENSEE under this Agreement, LICENSEE shall pay MCGRI the following royalties based on the Net Selling Price of the applicable Licensed Products Sold by LICENSEE:

Therapeutics (cancer/non-cancer) 3%

Diagnostics 4%

Reagents/Lab Consumables 5%

Notwithstanding the foregoing, if Licensee is required to pay a royalty under a patent license from any third party in order to sell a Licensed Product, then Licensee may reduce the royalty otherwise payable to MCGRI on the Net Selling Price of such Licensed Product by 50% of the royalty amounts paid to such third party; provided, however, that in no event will the royalty payable to MCGRI hereunder with respect to such Licensed Product be reduced by to less than 1.5%. Royalties shall be payable on a Licensed Product-by-Licensed Product and country-by-country basis from first commercial sale of a

Licensed Product in a country until the expiration of the last to expire valid claim of the Licensed Patents claiming the manufacture, use or sale of such Licensed Product in such country.

4.4 Minimum Royalties. Prior to the first commercial sale of a Licensed Product, Licensee shall pay to MCGRI an annual license fee equal to Twelve Thousand Dollars ($12,000) per License Agreement Year, within sixty (60) days following the end of each License Agreement Year. Following the first commercial sale of a Licensed Product, within sixty (60) days after the end of each License Agreement Year during the term of this Agreement thereafter, if earned royalties for such License Agreement Year are less than Seventy Five Thousand Dollars ($75,000), Licensee will pay to MCGRI a minimum annual royalty equal to the difference (if any) between $75,000 and earned royalties for such year. For any partial year for which a minimum annual royalty is due hereunder, the amount of such minimum annual royalty shall be pro-rated based on a 365-day year.

4.5 Reimbursement for Patent Expenses. LICENSEE shall reimburse MCGRI for all reasonable, documented out-of-pocket fees, costs, and expenses hereafter during the term of this Agreement paid or incurred by MCGRI in filing, prosecuting, and maintaining the Licensed Patents in the Licensed Territory. LICENSEE shall provide such reimbursement for patent expenses within 30 days of receipt of the itemized invoice.

4.6 Milestone Payments to MCGRI.

4.6.1 Within sixty (60) days of the first achievement by any Licensed Product of the following milestone events, Licensee shall pay (or issue) to MCGRI the indicated consideration:

4.6.1.1 IND Filing $15,000 and 5,000 shares of

Licensee’s common stock (as adjusted for any stock dividends, combinations, splits, recapitalizations, and the like occurring after the effective date of the Agreement)

4.6.1.2 Initiation of Phase II Clinical Trials $100,000

4.6.1.3 Completion of Phase III Clinical Trials $200,000

For clarity, each milestone payment above shall be due only once for a particular disease category (e.g., cancer, HIV, transplant), regardless of the number of molecules directed towards such disease category or the number of indications pursued in a particular disease category.

4.6.1.4 Within sixty (60) days of the achievement by each Licensed Product of the following milestone events, Licensee shall pay to MCGRI the indicated amount:

4.6.1.5 NDA approval in U.S. $1,500,000

4.6.1.6 Marketing approval in another country $1,000,000

For clarity, each milestone payment indicated above shall be due each time the milestone event is achieved by one or more Licensed Products.

ARTICLE 5. REPORTS AND PAYMENTS

5.1 Within sixty (60) days of September 30, December 31, March 31, and June 30 of each year during the term of this Agreement, up to and including September 30, December 31, March 31 and June 30 following the termination or expiration of this Agreement, LICENSEE shall render a written report to MCGRI setting forth for the preceding calendar quarter, the following as may be applicable under the royalty provisions hereof:

(a) the Net Selling Price of all Licensed Products Sold by LICENSEE, and its Affiliates and Sublicensees under this Agreement; and

(b) the amount of royalty payable; and

(c) any other information reasonably necessary to show the basis on which such royalty has been computed; and

(d) the title of the Licensed Patent(s), the Inventor(s), and the five digit MCG code(s) for the Licensed Patent(s); and

(e) in case no payment is due for any calendar quarter hereunder, LICENSEE shall so report.

5.2 Each royalty report shall be accompanied by the payment of all royalties due for the quarter calendar year in question. Any minimum royalty payment due under Article 4 shall accompany the report for the quarter ending on June 30 of the applicable License Agreement Year.

5.3 All royalties shall be paid in United States funds collectible at one hundred percent (100%) of face value in New York, New York, U.S.A. For purposes of computing the royalty payment on Sales outside the United States, the royalty payment hereunder shall first be determined in the foreign currency of the country in which Licensed Products are Sold and then converted to United States dollars at the spot rate published by the Wall Street Journal (U.S. edition) on the last day of the quarter for which payment is due.

5.4 In high inflation countries where LICENSEE uses accounting treatment under Statement of Financial Accounting Standards No. 52, Paragraph 11, or the successor equivalent Standard, LICENSEE may for each such country at the end of each quarter convert each month's Sales in that quarter to United States dollars by assuming all Sales in that month occurred on the last day of the month, computing the collection date for that month's Sales to United States dollars at the forecasted exchange rate for that computed collection date; differences between the forecasted exchange rate and the actual exchange rate are to be corrected in the first quarter in which known.

5.5 If Licensed Products are Sold in a country in which conditions or legal restrictions exist which prohibit remittance of United States dollars, LICENSEE shall have the right and option to make the royalty payment for such country by depositing the amount thereof in the currency of the country of Sale at LICENSEE's election, to MCGRI's account in a bank designated by MCGRI in such country.

5.6 Interest. Payments required under this Agreement shall, if overdue, bear interest until payment at a per annum rate two percent (2%) above the prime rate in effect at the Trust Company Bank in Atlanta, Georgia, on the due date. The payment of such interest shall not foreclose MCGRI from exercising any other rights it may have because any payment is late.

5.7 All payments and reports due under this Agreement shall be made in person or via the United States mail or private carrier to the following address:

Office of Technology Transfer and Economic Development

Medical College of Georgia

Attn: Associate Vice President of Technology Transfer & Economic Development

CA-2125

Medical College of Georgia

Augusta, Georgia 30912-9824
Facsimile: (706) 721-2917

5.8 All payments should be made payable to: The Medical College of Georgia Research Institute.

ARTICLE 6. RECORDS

6.1 Records of Sales. During the term of this Agreement and for a period of three (3) years thereafter, LICENSEE shall keep at its principal place of business true and accurate records of all Sales in accordance with general accepted accounting principles in the respective country where such Sales occur and in such form and manner so that all royalties owed to MCGRI may be readily and accurately determined. LICENSEE shall furnish MCGRI copies of such records upon MCGRI's request, which shall not be made more often than once per License Agreement Year.

6.2 Audit of Records. MCGRI shall have the right, from time to time at reasonable times during normal business hours through an independent certified public accountant, to examine the records of LICENSEE in order to verify the calculation of any royalties payable under this Agreement. Such examination and verification shall not occur more than once each License Agreement Year and the calendar year immediately following termination of this Agreement. Unless otherwise agreed in writing by LICENSEE, the fees and expenses of performing such examination and verification shall be borne by MCGRI. If such examination reveals an underpayment by LICENSEE of more than five percent (5%) for any quarter examined, LICENSEE shall pay MCGRI the amount of such underpayment plus interest and shall reimburse MCGRI for all expenses of the accountant performing the examination.

ARTICLE 7. PATENT PROSECUTION

7.1 Prosecution and Maintenance of Licensed Patents. The prosecution and maintenance of the Licensed Patents shall be the primary responsibility of MCGRI using counsel reasonably acceptable to LICENSEE. MCGRI shall keep LICENSEE informed as to all developments with respect to Licensed Patents, including by providing LICENSEE, in a timely manner prior to their due date, with copies of all official documents and correspondence relating to the prosecution, maintenance, and validity of the Licensed Patents. LICENSEE shall be afforded reasonable opportunities to advise MCGRI and cooperate with MCGRI in such prosecution and maintenance. LICENSEE shall advise MCGRI in which countries LICENSEE desires patents be filed, and MCGRI will comply with any such requests. MCGRI shall not unreasonably withhold consent to amend any patent application to include any claims related to Licensed Patents and/or Licensed Technology reasonably requested by LICENSEE to protect the Licensed Products

contemplated to be sold under this Agreement. If LICENSEE should fail to timely make reimbursement for patent expenses incurred under this paragraph as required in Article 4.5 of this Agreement, MCGRI shall have no further obligation to prosecute or maintain the Licensed Patents. MCGRI shall not finally abandon prosecution of any patent application without first notifying LICENSEE sixty (60) days prior to any bar date, of MCGRI's intention and reason therefore, and providing LICENSEE with reasonable opportunity to assume responsibility for prosecution, maintenance and associated costs of such Licensed Patents.

LICENSEE, upon ninety (90) days advance written notice to MCGRI, may advise MCGRI that it no longer wishes to pay expenses for filing, prosecuting or maintaining one or more Licensed Patents. MCGRI may, at its option, elect to pay such expenses or permit such Licensed Patents to become abandoned or lapsed. If MCGRI elects to pay such expenses, such patents shall not be subject to any license granted to LICENSEE hereunder.

7.2 Extension of Licensed Patents. LICENSEE may request that MCGRI have the normal term of any Licensed Patent extended or restored under a country's procedure of extending life for time lost in government regulatory approval processes, and the expense of same shall be borne in accordance with the terms of Article 4.5. LICENSEE shall assist MCGRI to take whatever action is necessary to obtain such extension. In the case of such extension, royalties pursuant to Article 4 hereof shall be payable until the end of the extended life of the patent. In the event that LICENSEE does not elect to extend Licensed Patent(s), MCGRI may, at its own expense, effect the extension of such Licensed Patent(s). If MCGRI elects to pay such expenses, such extended Licensed Patents shall not be subject to any license granted to LICENSEE hereunder.

ARTICLE 8. ABATEMENT OF INFRINGEMENT

8.1 Each party shall promptly inform the other party of any suspected infringement of any Licensed Patents. During the term of this Agreement, MCGRI and LICENSEE shall have the right to institute an action for infringement of the Licensed Patents against any such third party in accordance with the following and subject to the rights of any third parties granted licenses to practice the Licensed Patents by MCGRI:

(a) If MCGRI and LICENSEE agree to institute suit jointly, the suit shall be brought in both their names, the out-of-pocket costs thereof shall be borne equally, and any recovery or settlement shall be shared equally. LICENSEE and MCGRI shall agree upon the manner in which they shall exercise control over such action. MCGRI may, if it so desires, also be represented by separate counsel of its own selection. The fees for which counsel shall be paid by MCGRI;

(b) In the absence of agreement to institute a suit jointly, MCGRI may institute suit, and, at its option, name LICENSEE as a plaintiff. MCGRI shall bear the entire cost of such litigation and shall be entitled to retain the entire amount of any recovery or settlement; and

(c) In the absence of agreement to institute a suit jointly and if MCGRI notifies LICENSEE that it has decided not to join in or institute a suit, as provided in (a) or (b) above, LICENSEE may institute suit and, at its option, name MCGRI as a plaintiff. LICENSEE shall bear the entire cost of such litigation, including defending any counterclaims brought against MCGRI and paying any judgments rendered against MCGRI, and shall be entitled to retain the entire amount of any recovery or settlement.

8.2 Should either MCGRI or LICENSEE commence a suit under the provisions of this Article and thereafter elect to abandon such suit, the abandoning party shall give timely notice to the other party who may, if it so desires, continue prosecution of such suit, provided that the sharing of expenses and any recovery in such suit shall be as agreed upon between MCGRI and LICENSEE.

ARTICLE 9. CONFIDENTIALITY

9.1 LICENSEE shall not, without the express written consent of MCGRI, for any reason or at any time either during or subsequent to the term of this Agreement disclose any information contained in the Licensed Patents or Licensed Technology or any other information pertaining to the Licensed Patents and Licensed Technology (collectively referred to as “Proprietary Information”) to third parties other than Affiliates and LICENSEE’s sublicensees. This obligation of nondisclosure shall not extend to information:

(a) which LICENSEE can demonstrate through documentation to have been within LICENSEE’s legitimate possession prior to the time of disclosure of such information to LICENSEE by MCGRI, MCG, or the Inventors;

(b) which was in the public domain prior to disclosure by MCGRI, MCG, or the Inventors, as evidenced by documents published prior to such disclosure;

(c) which, after disclosure by MCGRI, MCG, or the Inventors, comes into the public domain through no fault of LICENSEE;

(d) which is disclosed to LICENSEE by a third party having legitimate possession of the information and the unrestricted right to make such disclosure.

(e) which is required by a valid court order or law, in which case each party would notify the other.

9.2 All reports provided to MCGRI pursuant to this Agreement shall be treated as confidential information of Licensee and shall not be disclosed to any third party without the prior written consent of Licensee. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party; provided, however, that disclosures may be made as required by securities or other applicable laws, or to actual or prospective investors or corporate partners, or to a party’s accountants, attorneys, and other professional advisors.

9.3 Prior Agreements. The provisions of this Agreement supersede and shall be substituted for any terms of any prior confidentiality agreement between LICENSEE and MCGRI which are not consistent with this Agreement.

ARTICLE 10. MERCHANTABILITY AND EXCLUSION OF WARRANTIES

10.1 LICENSEE possesses the necessary expertise and skill in the technical areas in which the Licensed Products and Licensed Technology are involved to make, and has made, its own evaluation of the capabilities, safety, utility, and commercial application of the Licensed Patents and Licensed Technology. ACCORDINGLY, to the best of MCGRI's knowledge based on reasonable inquiry, MCGRI represents and warrants that: (i) the execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate action on the part of MCGRI; (ii) MCGRI is the sole and exclusive owner of all right, title, and interest in the Licensed Patents; (iii) it has the right to grant the rights and licenses granted herein; (iv) it has not granted any third party any license, right or interest in any of the Licensed Patents that is inconsistent with the rights granted to Licensee herein and will not grant any third party such a right during the term of this Agreement; and (v) there are no threatened or pending actions, suits, investigations, claims, or proceedings in any way relating to the Licensed Patents.

10.2 Except as expressly set forth in Section 10.1, MCGRI MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE LICENSED PATENTS OR LICENSED TECHNOLOGY AND EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ANY OTHER IMPLIED WARRANTIES WITH RESPECT TO THE CAPABILITIES, SAFETY, UTILITY, OR COMMERCIAL APPLICATION OF LICENSED PATENTS OR LICENSED TECHNOLOGY.

ARTICLE 11. DAMAGES, INDEMNIFICATION, AND INSURANCE

11.1 NO LIABILITY. MCGRI shall not be liable to LICENSEE or LICENSEE's customers for special, incidental, indirect, or consequential damages resulting from defects in the design, testing, labeling, manufacture, or other application of Licensed Products manufactured, tested, designed, or Sold pursuant to this Agreement.

11.2 Indemnification. LICENSEE shall defend, indemnify, and hold harmless the Indemnitees from and against any and all loss, liability, expense, or damage (including investigative costs, court costs and attorneys' fees) Indemnitees may suffer, pay, or incur as a result of claims, demands or actions brought by a third party against any of the Indemnitees arising or alleged to arise by reason of or in connection with any and all personal injury and property damage caused or contributed to in whole or in part by LICENSEE's manufacture, testing, design, use, sale, or labeling of any Licensed Products, or the practice of any Licensed Patents, except, in each case, to the extent such claims, demands or actions result from the gross negligence or willful misconduct of any Indemnitee or the breach by MCGRI of any warranty, representation, covenant or agreement made by MCGRI in this Agreement. LICENSEE's obligations under this Article shall survive the expiration or termination of this Agreement for any reason.

11.3 Insurance. Without limiting LICENSEE's indemnity obligations under the preceding paragraph, LICENSEE shall maintain throughout the term of this Agreement and for ten (10) years thereafter a liability insurance policy which:

(a) insures Indemnitees for all claims, damages, and actions mentioned in Article 10.1 of this Agreement;

(b) includes a contractual endorsement providing coverage for all liability which may be incurred by Indemnitees in connection with this Agreement;

(c) requires the insurance carrier to provide MCGRI with no less than thirty (30) days written notice of any change in the terms or coverage of the policy or its cancellation; and

(d) prior to the initiation of the first clinical trial involving a Licensed Product, provides product liability coverage in an amount no less than two million dollars ($2,000,000) per

occurrence for bodily injury and one million dollars ($1,000,000) per occurrence for property damage, subject to a reasonable aggregate amount.

11.4 Notice of Claims. LICENSEE shall promptly notify MCGRI of all claims involving the Indemnitees and will advise MCGRI of the policy amounts that might be needed to defend and pay any such claims.

ARTICLE 12. TERM AND TERMINATION

12.1 Term. Unless sooner terminated as otherwise provided in this Agreement, the term of this Agreement shall commence on the date hereof and shall continue until the date of expiration of the last to expire of the Licensed Patents, including any renewals or extensions thereof.

12.2 Termination. MCGRI shall have the right to terminate this Agreement upon the occurrence of any one or more of the following events:

(a) failure of LICENSEE to make any two payments consecutive required pursuant to this Agreement when due; or

(b) failure of LICENSEE to render reports to MCGRI as required by this Agreement; or

(c) failure of LICENSEE to notify MCGRI of intent to file bankruptcy as set forth in Article 12.3 below;

(d) the insolvency of LICENSEE; or

(e) the institution of any proceeding by LICENSEE under any bankruptcy, insolvency, or moratorium law; or

(f) any assignment by LICENSEE of substantially all of its assets for the benefit of creditors; or

(g) placement of LICENSEE's assets in the hands of a trustee or a receiver unless the receivership or trust is dissolved within thirty (30) days thereafter; or

(h) the breach of any other material term of this Agreement.

12.3 Notice of Bankruptcy. The LICENSEE must inform MCGRI of its intention to file a voluntary petition in bankruptcy or of another's intention to file an involuntary petition in bankruptcy to be received at least thirty (30) days prior to filing such a petition. A party's filing without conforming to this requirement shall be deemed a material, pre-petition incurable breach.

12.4 Exercise. MCGRI may exercise its right of termination by giving LICENSEE, its trustees or receivers or assigns, thirty (30) days prior written notice of MCGRI's election to terminate. Upon the expiration of such period, this Agreement shall automatically terminate unless the LICENSEE has cured the breach. Such notice and termination shall not prejudice MCGRI's right to receive royalties or other sums due hereunder and shall not prejudice any cause of action of claim of MCGRI accrued or to accrue on account of any breach or default by LICENSEE.

12.5 Failure to Enforce. The failure of MCGRI at any time, or for any period of time, to enforce any of the provisions of this Agreement shall not be construed as a waiver of such provisions or as a waiver of the right of MCGRI thereafter to enforce each and every such provision.

12.6 Termination by LICENSEE. LICENSEE shall have the right to terminate this Agreement upon the occurrence the breach of a material term of this Agreement by MCGRI. In addition, LICENSEE may, upon sixty (60) days written notice to MCGRI, terminate this Agreement by doing all of the following: ceasing to make, have made, use, import, sell and offer for sale all Licensed Products; returning any confidential materials provided to Licensee by MCGRI in connection with this Agreement; paying all amounts owed to MCGRI under this Agreement, up to the date of termination.

12.7 Exercise. LICENSEE may exercise its right of termination based upon a material breach of this Agreement by MCGRI by giving MCGRI thirty (30) days prior written notice of LICENSEE's election to terminate. Upon the expiration of such period, this Agreement shall automatically terminate unless MCGRI has cured the breach. Such notice and termination shall not prejudice LICENSEE's right to pursue any other remedies available to LICENSEE at law.

12.8 Effect. In the event this Agreement is terminated for any reason whatsoever, LICENSEE shall return, or at MCGRI's direction destroy, all plans, drawings, papers, notes, writings and other documents, samples, organisms, biological materials and models pertaining to the Licensed Patents and Licensed Technology, retaining no copies, and shall refrain from using or publishing any portion of the Licensed Patents or Licensed Technology as provided in Article 8 of this Agreement. Upon termination of this Agreement, LICENSEE shall cease manufacturing, processing, producing, using, Selling, or distributing Licensed Products; provided, however, that LICENSEE may continue to Sell in the ordinary course of business for a period of one (1) year reasonable quantities of Licensed Products which are fully manufactured and in LICENSEE's normal inventory at the date of termination if (a) all monetary obligations of LICENSEE to MCGRI have been satisfied and (b) royalties on such sales are paid to MCGRI in the amounts and in the manner' provided in this Agreement. The provisions of Articles 9, 10, and 11 of this Agreement shall remain in full force and effect notwithstanding the termination of this Agreement.

ARTICLE 13. ASSIGNMENT

This Agreement is dependent upon the special relationship between the parties and the special knowledge and unique skills of the LICENSEE. Therefore, LICENSEE shall not grant, transfer, convey, or otherwise assign any of its rights or delegate any of its obligations under this Agreement without the prior written consent of MCGRI, except that Licensee may assign this Agreement without the prior written consent of MCGRI, to any Affiliate, or in connection with the transfer or sale of all or substantially all of Licensee's business to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise. This Agreement shall be assignable by MCGRI to MCG, or any other nonprofit corporation which promotes the education or research purposes of MCG.

ARTICLE 14. MISCELLANEOUS

14.1 Export Controls. LICENSEE acknowledges that MCGRI is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities and that MCGRI's obligations under this Agreement are contingent upon compliance with applicable United States export laws and regulations. The transfer of technical data and commodities may require a license from the cognizant agency of the United States government or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without the prior approval of certain United States agencies. MCGRI neither represents that an export license shall not be required nor that, if required, such export license shall issue.

14.2 Legal Compliance. LICENSEE shall comply with all laws and regulations applicable to its manufacture, processing, producing, use, Selling, or distributing of Licensed Products.

14.3 Independent Contractor. LICENSEE's relationship to MCGRI shall be that of a licensee only. LICENSEE shall not be the agent of MCGRI and shall have no authority to act for or on behalf of MCGRI in any matter. Persons retained by LICENSEE as employees or agents shall not by reason thereof be deemed to be employees or agents of MCGRI.

14.4 Patent Marking. LICENSEE shall mark Licensed Products Sold in the United States with United States patent numbers. Licensed Products manufactured or Sold in other countries shall be marked in compliance with the intellectual property laws in force in such foreign countries.

14.5 Use of Names. LICENSEE shall obtain the prior written approval of MCGRI, MCG, or the Inventors prior to making use of their names for any commercial purpose.

14.6 Place of Execution. This Agreement and any subsequent modifications or amendments hereto shall be deemed to have been executed in the State of Georgia, U.S.A. This Agreement shall not become effective or binding upon MCGRI until signed on its behalf by its Executive Director in the State of Georgia, U.S.A.

14.7 Governing Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the parties hereunder, shall be construed under and governed by the laws of the State of Georgia and the United States of America. Only courts in the State of Georgia, U.S.A., shall have jurisdiction to hear and decide any controversy or claim between the parties arising under or relating to this Agreement.

14.8 Entire Agreement. This Agreement constitutes the entire agreement between MCGRI and LICENSEE with respect to the subject matter hereof and shall not be modified, amended or terminated except as herein provided or except by another agreement in writing executed by the parties hereto.

14.9 Severability. All rights and restrictions contained herein may be exercised and shall be applicable and binding only to the extent that they do not violate any applicable laws and are intended to be limited to the extent necessary so that they will not render this Agreement illegal, invalid or unenforceable. If any provision or portion of any provision of this Agreement not essential to the commercial purpose of this Agreement shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, it is the intention of the parties that the remaining provisions or portions thereof shall constitute their agreement with respect to the subject matter hereof, and all such remaining provisions or portions thereof shall remain in full force and effect. To the extent legally permissible, any illegal, invalid or unenforceable provision of this Agreement shall be replaced by a valid provision which will implement the commercial purpose of the illegal, invalid or unenforceable provision. In the event that any provision essential to the commercial purpose of this Agreement is held to be illegal, invalid or

unenforceable and cannot be replaced by a valid provision which will implement the commercial purpose of this Agreement, this Agreement and the rights granted herein shall terminate.

14.10 Force Majeure. Any delays in, or failure of, performance of any party to this Agreement shall not constitute default hereunder, or give rise to any claim for damages, if and to the extent caused by occurrences beyond the control of the party affected, including, but not limited to, acts of God, strikes or other work stoppages; civil disturbances, fires, floods, explosions, riots, war, rebellion, sabotage, acts of governmental authority or failure of governmental authority to issue licenses or approvals which may be required.

ARTICLE 15. NOTICES

All notices, statements, and reports required or contemplated herein by one party to the other shall be in writing and shall be deemed to have been given upon delivery in person or upon the expiration of five (5) days after deposit in a lawful mail depository in the country of residence of the party giving the notice, registered or certified airmail postage prepaid, and addressed as follows:

If to MCGRI:

Associate Vice President

Office of Technology Transfer & Economic Development
Medical College of Georgia Research Institute, Inc.
CA-2125
Medical College of Georgia
Augusta, Georgia 30912-9824
Facsimile: (706) 721-2917

With a copy to: Legal Advisor

Medical College of Georgia Research Institute, Inc.
CJ-3301
Medical College of Georgia
Augusta, Georgia 30912-4810
Facsimile: (706) 721-7603

If to LICENSEE: NewLink Genetics Corporation

Chief Medical Officer
2901 South Loop Dr, Suite 3900

Ames, IA 50010
Facsimile: (515) 296-5557

Either party hereto may change the address to which notices to such party are to be sent by giving notice to the other party at the address and in the manner provided above. Any notice herein required or permitted to be given may be given, in addition to the manner set forth above, by telex, facsimile or cable, provided that the party giving such notice obtains acknowledgement by telex, facsimile or cable that such notice has been received by the party to be notified. Notice made in this manner shall be deemed to have been given when such acknowledgement has been transmitted.

IN WITNESS WHEREOF, MCGRI and LICENSEE have caused this Agreement to be signed by their duly authorized representatives as of the day and year indicated below.

MEDICAL COLLEGE OF GEORGIA	LICENSEE:
RESEARCH INSTITUTE, INC.	NEWLINK GENETICS CORPORATION
By: /s/ Betty Aldridge	By: /s/ Nicholas Vahanian
Name: Betty Aldridge	Name: Nicholas Vahanian
Title: Executive Director	Title: Chief Medical and Operations Officer

EXHIBIT A

LICENSED PATENTS

Case # 007-98 “Regulation of T-Cell Mediated Immunity by Tryptophan”

U.S. Patent No. 6,451,840
Inventors: D. Munn and A. Mellor

Case # 007-98 Div 1 “Regulation of T-Cell Medicated Immunity by Tryptophan”

U.S. Patent No. 6,482,416
Inventors: D. Munn and A. Mellor

Case # 007-98 Div 2 “Regulation of T-Cell Medicated Immunity by Tryptophan”

U.S. Non-Provisional/Regular Patent Application # 10/112,362
Inventors: D. Munn and A. Mellor

Case # 011-98 “High Affinity Tryptophan Transporter”

U.S. Patent No. 6,395,876
Inventors: D. Munn and A. Mellor

Case # 011-02 “Antigen-Presenting Cell Populations and Their Use as Reagents for Enhancing or Reducing Immune Tolerance”

U.S. Non-Provisional/Regular Patent Application 10/121,909
Inventors: D. Munn and A. Mellor

Case # 003-03 “Chemokine Receptor Antagonists as Therapeutic Agents”

U.S. Non-Provisional/Regular Patent Application # 10/660,131
Inventors: D. Munn, A. Mellor and S. Peiper

Case # 009-03 “Regulation of T Cell-Mediated Immunity by D Isomers of Inhibitors of Indoleamine-2,3 -Dioxygenase

U.S. Provisional Patent Application 60/459,489

Inventors: D. Munn and A. Mellor

EXHIBIT B

STOCK SUBSCRIPTION AGREEMENT

This Stock Subscription Agreement (the "**Agreement**") is made as of the 13 day of September, 2005, by and between NewLink Genetics Corporation, a Delaware corporation (the "**Company**"), and Medical College of Georgia Research Institution, Inc., a nonprofit Georgia corporation ("**Purchaser**").

W I T N E S S E T H:

WHEREAS, pursuant to the terms of the License Agreement, dated this date, between the Company and the Purchaser (the "**License Agreement**"), the Company has agreed to issue and sell to Purchaser, and Purchaser desires to acquire, twenty-five thousand (25,000) shares of Common Stock (the "**Common Stock**") of the Company.

NOW, THEREFORE, IT IS AGREED between the parties as follows:

1. **Purchase and Sale; Closing.**

(a) For and in consideration of the license granted pursuant to the License Agreement, Purchaser hereby agrees to Purchase from the Company and the Company agrees to issue and sell to Purchaser twenty-five thousand (25,000) shares of Common Stock (the "**Shares**").

(b) The Company delivers herewith to Purchaser a certificate registered in Purchaser's name representing the number of Shares purchased hereunder. Purchaser and the Company agree that the value of the Shares is $85,000 ($3.40 per share).

2. Representations and Warranties of the Purchaser.

Purchaser hereby represents and warrants to the Company as follows:

(a) Purchaser is aware that the Shares to be issued to Purchaser by the Company pursuant to this Agreement have not been registered under the Securities Act of 1933, as amended (the "**Act**"), and that the Shares are deemed to constitute "restricted securities" under Rule 144 promulgated under the Act.

(b) Purchaser is obtaining the Shares for Purchaser's own account and Purchaser has no present intention of distributing or selling said Shares except as permitted under the Act and applicable state securities laws. Purchaser does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person with respect to any of the Shares and Purchaser knows of no public solicitation or advertisement of any offer in connection with the Shares. Purchaser represents that Purchaser has full power and authority to enter into this Agreement.

(c) Purchaser is aware that the purchase of the Shares involves a high degree of risk. Purchaser acknowledges that Purchaser is able to fend for itself, can bear the economic risk of such investment, and has sufficient knowledge and experience in business and financial matters that Purchaser is capable of evaluating the Company, its proposed activities and the risks and merits of the investment in the Shares. Purchaser has the ability to accept the high risk and lack of liquidity inherent in this type of investment.

(d) Purchaser understands that the exemption from registration under Rule 144 will not be available for at least two years from the date of receipt of the Shares unless at least one year from the date of receipt (i) a public trading market then exists for the Common Stock of the Company, (ii) adequate information concerning the Company is then available to the public, and (iii) other terms and conditions of Rule 144 are complied with; and that any sale of the Shares may be made only in limited amounts in accordance with such terms and conditions and that after ninety days after the Company becomes subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Shares may be resold by persons other than affiliates in reliance on Rule 144 without compliance with paragraphs (c), (d), (e) and (h) thereof, and by affiliates without compliance with paragraph (d) thereof.

(e) Purchaser is familiar with the Company, the nature of its business, its financial prospects and the merits and risks of an investment in the Company, and has the capacity to protect Purchaser's own interests. Purchaser has been provided with the Company's financial statements and executive summary and has had an opportunity to discuss the Company's business, management and financial affairs with directors, officers and management of the Company. Purchaser has also had the opportunity to ask

questions of, and receive answers from the Company and its management regarding the terms and conditions of this investment.

(g) Purchaser is an “accredited investor” as defined in Rule 501 under the Act.

3. Restrictive Legends.

All certificates representing the Shares shall have endorsed thereon the following legends:

(a) “THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND THUS MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF UNLESS REGISTERED UNDER APPLICABLE FEDERAL OR STATE SECURITIES LAWS, OR UNLESS THE COMPANY IS FURNISHED WITH AN OPINION OF COUNSEL ACCEPTABLE TO IT THAT AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.”

(b) “THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO A RIGHT OF FIRST REFUSAL OPTION IN FAVOR OF THE CORPORATION AND/OR ITS ASSIGNEE(S), AS PROVIDED IN THE BYLAWS OF THE CORPORATION.”

(c) Any legend required to be placed thereon by appropriate state Blue Sky officials.

4. Restrictions on Transfer.

(a) Without in any way limiting the foregoing, Purchaser further agrees that Purchaser shall in no event make any disposition of all or any portion of the Shares which Purchaser is being issued unless and until: (i) there is then in effect a registration statement under the Act covering such proposed disposition and such disposition is made in accordance with said registration statement; (ii) such disposition is made in accordance with the provisions of the Company’s Bylaws, (iii) Purchaser shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and (iv) if reasonably requested by the Company, such Purchaser shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, that such disposition will not require registration of such shares under the Act. It is agreed that the Company will not require opinions of counsel for transactions made pursuant to Rule 144 except in unusual circumstances.

(b) Purchaser hereby agrees that for a period of 180 days following the effective date of the first registration statement of the Company covering Common Stock (or other securities) to be sold on its behalf in an underwritten public offering, Purchaser shall not, to the extent requested by the Company and any underwriter, sell or otherwise transfer or dispose of (other than to donees who agree to be similarly bound) any Common Stock of the Company held by Purchaser at any time during such period except Common Stock included in such registration.

(c) In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Common Stock held by Purchaser (and the shares or securities of every other person subject to the foregoing restriction) until the end of such period.

(d) The Company shall not be required (i) to transfer on its books any Shares which shall have been sold or transferred in violation of any of the provisions set forth in this Bylaws or (ii) to treat as owner of such Shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Shares shall have been so transferred.

5. Miscellaneous.

(a) The parties agree to execute such further instruments and to take such further action as may reasonably be necessary to carry out the intent of this Agreement.

(b) Unless otherwise provided, any notice or other communications required or permitted under this Agreement shall be given in writing and shall be mailed by United States first class mail, postage prepaid, sent by facsimile or delivered personally by hand or by a nationally recognized courier addressed to the party to be notified at the address or facsimile number indicated for such person on the signature page hereof, or at such other address or such facsimile number as such party may designate by ten (10)

days' advance written notice to the other parties hereto. All such notices and other written communications shall be effective on the date of mailing, confirmed facsimile transfer or delivery.

(c) This Agreement shall be governed by the laws of the State of Iowa and interpreted and determined in accordance with the laws of the State of Iowa, as such laws are applied by Iowa courts to contracts made and to be performed entirely in Iowa by residents of that state.

(d) This Agreement shall inure to the benefit of the successors and assigns of the Company and, subject to the restrictions on transfer herein set forth, shall be binding upon Purchaser, his or her heirs, executors, administrators, successors and assigns.

(e) This Agreement constitutes the full and entire understanding and agreement of the parties with respect to the subject matter hereof and no party shall be liable or bound to any other in any manner by any representations, warranties, covenants and agreements except as specifically set forth herein.

(f) The warranties, representations and covenants of the Purchaser contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement and the Closing.

IN WITNESS WHEREOF**,** the parties hereto have executed this Agreement as of the day and year first above written.

NewLink Genetics Corporation

By: /s/ Nicholas N. Vahanian

Title: Chief Medical & Operations Officer

Address: 2901 S. Loop Drive #3900

Ames, IA 50010

Facsimile No.: (515) 296-5557

Purchaser:

Medical College of Georgia Research Institution, Inc.

By: /s/ Betty Aldridge
Title: Executive Director, MCG Research Institute
Address: CA-2125, 1120 15th Street
Augusta, GA 30901
Facsimile No.: 706/721-2917

Exhibit 10.1.1

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its inhibitors in Immuno-regulation (MCG case # 007-98, 011-98, 011-02, 003-03, 009-03) dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was

signed

and

Inasmuch as the NewLink has reviewed a new Improvement Technology (MCG case # 032-05: IDO Role in Generation of Regulatory T-cells and Immunological Tolerance, by A. Mellor, D. Munn, B. Blazar, and W. Chen; jointly owned with the University of Minnesota), and wishes to exercise its option to incorporate this technology into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case # 032-05 is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of $20,000 is received at MCGRI.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE	NEWLINK GENETICS
By /s/Betty Aldridge	By: /s/Nicholas N. Vahanian
Name: Betty Aldridge	Name: Nicholas N. Vahanian
Title: Executive Director	Title: Chief Medical and Operations Office
Date: 4/27/06	Date: 4/21/06

Exhibit 10.1.2

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its Inhibitors in Immuno-regulation (MCG case # 007-98, 011-98, 011-02, 003-03, 009-03) dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was signed

and

Inasmuch as NewLink has reviewed a new Improvement Technology (MCG case # 005- 06: CpG Oligonucleotides Induce Spleen Cells to Acquire IDO-dependent Regulatory Functions, by D. Munn and A. Mellor), and wishes to exercise its option to incorporate those technologies into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case #005-06 is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of $20,000 is received at MCGRI.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE

By /s/Betty Aldridge
Name: Betty Aldridge
Title: Executive Director
Date: 4/27/06

NEWLINK GENETICS

By: /s/Nicholas N. Vahanian
Name: Nicholas N. Vahanian
Title: Chief Medical and Operations Office
Date: 4/21/06

Exhibit 10.1.3

LICENSE AGREEMENT AMENDMENT

Inasmuch as NewLink Genetics Corporation of Ames, Iowa, and the Medical College of Georgia Research Institute of Augusta Georgia, have a valid and existing License Agreement related to the use of Indoleamine-2,3-Dioxygenase and its Inhibitors in Immuno-regulation (MCG case # 007-98, 011-98, 011-02, 003-03, 009-03) dated September 13, 2005;

and

Inasmuch as the parties agree that the License Agreement contains a provision (Section 4.1) for the acquisition of new, related Improvement Technologies by NewLink arising at MCGRI after the Agreement was signed

and

Inasmuch as the NewLink has reviewed a new Improvement Technology (MCG case # 023-07:Synergy Between IDO Inhibitors and PD-1/PD-Ligand Antibodies, by A. Mellor, D. Munn, B. Blazar, and Madhav Sharma; jointly owned with the University of Minnesota), and wishes to exercise its option to incorporate this technology into the existing License Agreement technology portfolio under its standard royalty terms and use conditions,

It is Agreed:

That the parties amend the License Agreement relative to its Exhibit A , such that MCG case # 023-07 is to be included in the technology portfolio for development and commercialization by NewLink, effective the date that the License Fee of $20,000 is received at MCGRI. All Payments due to the University of Minnesota will be coordinated by MCGRI according to the terms stated in “Agreement For Joint Ownership and Commercialization for Case 023-07”, between MCG and the University of Minnesota.

This present amendment shall hereby be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA RESEARCH INSTITUTE	NEWLINK GENETICS
By /s/Betty Aldridge	By: /s/Nicholas N. Vahanian
Name: Betty Aldridge	Name: Nicholas N. Vahanian
Title: Executive Director	Title: Chief Medical and Operations Office
Date: 2/13/07	Date: 2/6/07

Exhibit 10.1.4

LICENSE AGREEMENT AMENDMENT

The following is an amendment to Exhibit A of the License Agreement between Medical College of Georgia and NewLink Genetics previously executed on September 13th, 2005. The purpose of this amendment is to explicitly list patent applications filed previously to the execution of this Agreement as continuations of Case # 009-03, and which were unintentionally ommited in the original Exhibit A. These missing patent applications are: Provisional US 60/538,647 and Non-Provisional Patents US 10/780,150 and US 10/780,797.

The present amendment should be considered part of the original License Agreement and is hereto agreed by representatives of both parties signing below.

MEDICAL COLLEGE OF GEORGIA

RESEARCH INSTITUTE
By: /s/ Betty Aldridge
Name: Betty Aldridge
Executive Director
MCG Research Institute
Title:
Date: 3/28/06

LICENSEE:

NEWLINK GENETICS
By: /s/ Nicholas Vahanian
Name: Nicholas Vahanian

Title: Chief Medical & Operations Officer
Date: 3/28/06

EXHIBIT A
LICENSED PATENTS

[Case #007-98	“Regulation of T-Cell Mediated Immunity by Tryptophan” U.S. Patent No. 6,451,840 Inventors: D. Munn and A. Mellor
Case #007-98 Div1	“Regulation of T-Cell Mediated Immunity by Tryptophan” U.S. Patent No. 6,482,416 Inventors: D. Munn and A. Mellor
Case #007-98 Div2	“Regulation of T-Cell Mediated Immunity by Tryptophan” U.S. non-Provisional/Regular Patent Application 10/112,362 Inventors: D. Munn and A. Mellor
Case #011-98	High Affinity Tryptophan Transporter” U.S. Patent No. 6,395,876 Inventors: D. Munn and A. Mellor
Case #011-02	“Antigen-Presenting Cell Populations and Their Use as Reagents for Enhancing of Reducing Immune Tolerance” U.S. non-Provisional/Regular Patent Application 10/121,909 Inventors: D. Munn and A. Mellor
Case #003-03	“Chemokine Receptor Antagonists as Therapeutic Agents” U.S. non-Provisional/Regular Patent Application 10/660,131 Inventors: D. Munn, A. Mellor and S. Peiper
Case #009-03	“Regulation of T Cell-Mediated Immunity by D Isomers of Inhibitors of Indoleamine-2,3-Dioxygenase” U.S. Provisional Patent Application 60/459,489 Inventors: D. Munn and A. Mellor
Case #009-03	“Inhibitors of Indoleamine-2,3-Dioxygenase and Methods of Use” U.S. Provisional Patent Application 60/538,647 Inventors: D. Munn and A. Mellor
Case #009-03	“Regulation of T Cell-Mediated Immunity by D Isomers of Inhibitors of Indoleamine-2,3-Dioxygenase” U.S. Non-Provisional/Regular Patent Application 10/780,150 Inventors: D. Munn and A. Mellor
Case #009-03	“Use of Inhibitors of Indoleamine-2,3-Dioxygenase in Combination with Other Therapeutic Modalities” U.S. Non-Provisional/Regular Patent Application 10/780,797 Inventors: D. Munn and A. Mellor]

AMENDMENT TO LICENSE AGREEMENT

This Amendment to License Agreement ("**Amendment**") is effective as of July 10, 2014 (the "**Amendment Effective Date**"), by and between Georgia Regents Research Institute, Inc. (formerly known as Georgia Health Sciences University Research Institute, Inc. which was formerly known as Medical College of Georgia Research Institute, Inc.) ("**GRRI**") and NewLink Genetics Corporation ("**NewLink**"). GRRI and NewLink are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, GRRI and NewLink are parties to that certain License Agreement dated as of September 13, 2005, and amended on March 28, 2006, April 27, 2006, February 13, 2007 and July 12, 2013 (the "**Agreement**"); and

WHEREAS, the Parties desire to amend the Agreement in accordance with Section 14.8 thereof;

NOW THEREFORE, in consideration of the premises and mutual covenants contained in this Amendment, the Parties agree as follows:

1. All references in the Agreement to MCGRI or GHSURI are hereby deemed references to GRRI.

2. Each reference to "Licensee" in Section 1.12 (the definition of "Net Selling Price") that is not part of the phrase "Licensee or its Affiliate" is hereby deleted and replaced with "Licensee or its Affiliate".

3. The second and third sentences of Section 2.5 are hereby deleted and replaced with the following:

   LICENSEE acknowledges that, in accordance with Public Law 96-517 and other statutes, regulations, and Executive Orders as now exist or may be amended or enacted, the United States government may have certain rights in the Licensed Patents and Licensed Technology. LICENSEE shall take all action necessary to enable GRRI to satisfy its obligations, if any, under any federal law relating to the Licensed Patents or Licensed Technology.

4. The following language shall be inserted as a new Section 2.7:

   2.7 Transfer of Intellectual Property Rights Between Affiliates. LICENSEE and each Affiliate of LICENSEE may transfer all or part of its right and license under the Licensed Patents and Licensed Technology pursuant to Section 2.1 to, as applicable, LICENSEE or another Affiliate of LICENSEE. For clarity, this Section 2.7 authorizes LICENSEE and its Affiliates to enter into agreements necessary to, as between LICENSEE and its Affiliates, consolidate the rights licensed to LICENSEE and its Affiliates (collectively, pursuant to Section 2.1 of this Agreement) solely in LICENSEE or a single Affiliate of LICENSEE. LICENSEE or an Affiliate shall provide to GRRI a copy of any such agreement or other document reflecting a transfer under this provision and any amendment thereto, including all attachments, exhibits, and/or addendums, within 30 days of execution; provided, however, such copies to GRRI may be redacted to exclude confidential information of the applicable Affiliate or of LICENSEE to the extent not relevant to GRRI, but such copies shall not be redacted to the extent that it impairs GRRI's ability to ensure compliance with this Agreement.

5. The first sentence of Section 4.2 is hereby deleted and replaced with the following:

   LICENSEE shall pay GRRI twenty five percent (25%) of any fees or payments or remuneration paid to LICENSEE or an Affiliate of LICENSEE by a Sublicensee in relation to this License and

for rights to all or part of the Licensed Patents other than: research funding (including purchase price of Licensed Products to be used by Sublicensee in connection with research and development activities), equity, loans, or patent costs or fee reimbursements.

6. Section 4.3 is hereby deleted and replaced with the following:

As partial consideration for the license granted to LICENSEE under this Agreement, LICENSEE shall pay GRRI the following royalties based on the Net Selling Price of the applicable Licensed Products sold by LICENSEE or an Affiliate of LICENSEE:

Therapeutics (cancer/non-cancer) 3%
Diagnostics 4%
Reagents/Lab Consumables 5%

Notwithstanding the foregoing, if LICENSEE or an Affiliate of LICENSEE is required to pay a royalty under a patent license from any third party in order to sell a Licensed Product, then LICENSEE may reduce the royalty otherwise payable to GRRI on the Net Selling Price of such Licensed Product by 50% of the royalty amounts paid to such third party; provided, however, that in no event will the royalty payable to GRRI hereunder with respect to such Licensed Product be reduced to less than 1.5%. Royalties shall be payable on a Licensed Product-by-Licensed Product and country-by-country basis from first commercial sale of a Licensed Product in a country until the expiration of the last to expire valid claim of the Licensed Patents claiming the manufacture, use or sale of such Licensed Product in such country.

7. Section 2.2 is hereby deleted and replaced with the following:

2.2 Sublicensing. Licensee and its Affiliates may sublicense to one or more third parties the rights granted under this Agreement, subject to the prior approval of GRRI, not to be unreasonably withheld or delayed. If this Agreement is terminated for any reason, any sublicenses granted shall remain in full force and effect and be directly enforceable by GRRI. Licensee or an Affiliate shall provide to GRRI a copy of any such sublicense and any amendment thereto, including all attachments, exhibits, and/or addendums, within 30 days of execution; provided, however, such copies to GRRI may be redacted to exclude confidential information of the applicable Sublicensee or of LICENSEE to the extent not relevant to GRRI, but such copies shall not be redacted to the extent that it impairs GRRI's ability to ensure compliance with this Agreement.

8. The first sentence of Section 9.2 shall be deleted and replaced with the following language:

The following shall be treated as confidential information of Licensee and shall not be disclosed to any third party without the prior written consent of Licensee: (i) all reports provided to GRRI pursuant to this Agreement and (ii) all documents provided to GRRI pursuant to Section 2.2 and Section 2.7 of this Agreement.

9. Except as expressly amended hereby, the terms and conditions of the Agreement shall remain unchanged and in full force and effect. In the event of any conflict between the terms of this Amendment and the terms of the Agreement, the terms of this Amendment shall govern. The amendments made herein shall be effective as of the Amendment Effective Date. Capitalized terms used in this Amendment that are not otherwise defined herein shall have the same meanings as such terms are given in the Agreement. For clarity, any cross-references to Agreement Sections refer to those Agreement Sections as amended by this Amendment. This Amendment may be executed in counterparts, each of which shall be deemed an original but all of which shall be considered one and the same instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Amendment by their duly authorized officers as of the date set forth above.

Georgia Regents Research Institute, Inc.

By:/s/ Sarah J. White
Name: Sarah J. White
Title: Executive Director
Georgia Regents Research Institute, Inc.
7-10-2014

NewLink Genetics Corporation

By: /s/ Gordon Link
Name: Gordon Link
Title: CFO

EXHIBIT 31.1

CERTIFICATION

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

1. I have reviewed this Form 10-Q of NewLink Genetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

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 Form 10-Q of NewLink Genetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

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 March 31, 2019, 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.

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of May, 2019.

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)

"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."