

NEWLINK GENETICS CORP

Form 10-Q

November 03, 2017

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017.

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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý 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 (Do not check if a smaller reporting company)

Smaller reporting company o

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

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any new or revised financial accounting standards provided pursuant to  
Section 13(a) of the Exchange Act. ☐

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

As of October 31, 2017, there were 37,077,159 shares of the registrant's Common Stock, par value \$0.01 per share,  
outstanding.

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## PART I

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

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 120,702	\$ 131,490
Prepaid expenses and other current assets	2,701	5,921
Income tax receivable	114	5,975
Other receivables	10,670	24,526
Total current assets	134,187	167,912
Property and equipment, net	5,527	6,835
Total assets	\$ 139,714	\$ 174,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 11,860	\$ 22,883
Accrued expenses	13,832	14,309
Current portion of unearned revenue	112	391
Current portion of deferred rent	93	90
Current portion of notes payable and obligations under capital leases	194	232
Total current liabilities	26,091	37,905
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	138	285
Deferred rent	1,021	1,091
Total long-term liabilities	7,159	7,376
Total liabilities	33,250	45,281
Stockholders' equity:		
Blank check preferred stock, \$0.01 par value: Authorized shares — 5,000,000 at September 30, 2017 and December 31, 2016; issued and outstanding shares — 0 at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.01 par value: Authorized shares — 75,000,000 at September 30, 2017 and December 31, 2016; issued 31,375,528 and 29,193,718 at September 30, 2017 and December 31, 2016, respectively, and outstanding 31,319,751 and 29,163,673 at September 30, 2017 and December 31, 2016, respectively	314	292
Additional paid-in capital	331,036	295,535
Treasury stock, at cost: 55,777 and 30,045 shares at September 30, 2017 and December 31, 2016, respectively	(1,113)	(853)
Accumulated deficit	(223,773)	(165,508)
Total stockholders' equity	106,464	129,466
Total liabilities and stockholders' equity	\$ 139,714	\$ 174,747
See accompanying notes to condensed consolidated financial statements.		



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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Grant revenue	\$5,379	\$14,457	\$18,279	\$20,057
Licensing and collaboration revenue	103	888	334	3,008
Total operating revenues	5,482	15,345	18,613	23,065
Operating expenses:				
Research and development	18,480	24,463	52,405	73,810
General and administrative	7,907	7,749	25,038	26,043
Total operating expenses	26,387	32,212	77,443	99,853
Loss from operations	(20,905 )	(16,867 )	(58,830 )	(76,788 )
Other income and expense:				
Miscellaneous income (expense)	12	(44 )	(101 )	(44 )
Interest income	151	68	353	180
Interest expense	(3 )	(5 )	(116 )	(18 )
Other income, net	160	19	136	118
Net loss before taxes	(20,745 )	(16,848 )	(58,694 )	(76,670 )
Income tax benefit	119	1,308	429	5,021
Net loss	\$(20,626)	\$(15,540 )	\$(58,265)	\$(71,649 )
Basic and diluted loss per share	\$(0.69 )	\$(0.54 )	\$(1.98 )	\$(2.48 )

Basic and diluted average shares outstanding 29,939,823 28,983,561 29,462,226 28,911,042  
See accompanying notes to condensed consolidated financial statements.

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

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2016	29,163,673	\$ 292	\$ 295,535	\$(853 )	\$(165,508 )	\$ 129,466
Share-based compensation	—	—	14,938	—	—	14,938
Exercise of stock options and restricted stock vested	189,155	2	923	—	—	925
Sales of shares under stock purchase plan	51,999	1	325	—	—	326
Repurchase of common stock	(25,732 )	—	—	(260 )	—	(260 )
Issuance of common stock under the ATM Offering (net of offering costs of \$561)	1,940,656	19	19,315	—	—	19,334
Net loss	—	—	—	—	(58,265 )	(58,265 )
Balance at September 30, 2017	31,319,751	\$ 314	\$ 331,036	\$(1,113)	\$(223,773 )	\$ 106,464

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2017	2016
Cash Flows From Operating Activities		
Net loss	\$(58,265 )	\$(71,649 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	14,938	13,119
Depreciation and amortization	1,064	1,536
Forgiveness of debt	—	(397 )
Tax shortfall associated with employee stock plans	—	(640 )
Impairment of fixed assets	—	3,976
Loss on sale of fixed assets	102	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,220	(5,734 )
Other receivables	13,856	(9,607 )
Accounts payable and accrued expenses	(11,500 )	27,204
Income taxes receivable	5,861	(6,056 )
Unearned revenue	(279 )	(606 )
Deferred rent	(67 )	(79 )
Net cash used in operating activities	(31,070 )	(48,933 )
Cash Flows From Investing Activities		
Maturity of certificates of deposit	—	2,180
Purchase of equipment	(43 )	(2,069 )
Proceeds on sale of equipment	185	—
Net cash provided by investing activities	142	111
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	20,585	1,686
Repurchase of common stock	(260 )	(13 )
Payments under capital lease obligations and principal payments on notes payable	(185 )	(195 )
Net cash provided by financing activities	20,140	1,478
Net decrease in cash and cash equivalents	(10,788 )	(47,344 )
Cash and cash equivalents at beginning of period	131,490	195,620
Cash and cash equivalents at end of period	\$120,702	\$148,276
Supplemental disclosure of cash flows information:		
Cash paid for interest	\$11	\$18
Cash (refunds received) paid for taxes, net	\$(6,261 )	\$1,022
Noncash financing and investing activities:		
Equipment acquired by capital lease	\$—	\$231
Forgiveness of debt	\$—	\$397
See accompanying notes to condensed consolidated financial statements.		



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

1. Description of Business

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

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs. The Company incurred a net loss of \$20.6 million and \$58.3 million for the three and nine months ended September 30, 2017.

In July 2017, the Company undertook an organizational realignment to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Refer to Note 9 for more information.

The accompanying condensed consolidated financial statements as of September 30, 2017 and for the three and nine months ended have been prepared assuming the Company will continue as a going concern. The Company successfully raised net proceeds of \$37.6 million from its IPO, completed a follow-on offering of its common stock raising net proceeds of \$49.0 million, and raised an additional \$58.7 million in net proceeds from an at the market (ATM) offering completed in 2015.

On November 29, 2016, the Company entered into a Sales Agreement with Cantor Fitzgerald & Co. (Cantor) under which the Company may sell up to \$40.0 million of its common stock in one or more placements at prevailing market prices in an ATM offering. The Company launched this ATM offering in June 2017. During the three months ended September 30, 2017, 1,940,656 shares of the Company's common stock were sold under this ATM, with aggregate net proceeds of \$19.3 million after commissions of \$398,000 paid to Cantor as the placement agent, and other costs of \$163,000.

Subsequent to September 30, 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. In connection with two license and collaboration agreements the Company entered into during 2014, the Company received a nonrefundable upfront cash payment of \$150.0 million from Genentech Inc., a member of the Roche Group, or Genentech, in 2014, and a nonrefundable upfront cash payment of \$30.0 million from Merck, Sharpe and Dohme Corp., or Merck, in 2014, as well as a milestone payment of \$20.0 million from Merck in February 2015. The Company's cash and cash equivalents after these agreements and the offerings are expected to be adequate to satisfy the Company's liquidity requirements into the second quarter of 2020. If available liquidity becomes insufficient to meet the Company's operating obligations as they come due, the Company's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company's cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company's ability to continue as a going concern.

2. Basis of Presentation

The 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, 2016, included in the Company's Annual Report on Form 10-K. There were no significant changes in the Company's accounting policies since the end of fiscal 2016. The financial results for any interim period are not necessarily indicative of financial results for the full year.

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

3. Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the financial statements of NewLink and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Financial Instruments and Concentrations of Credit Risk

Cash and cash equivalents, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable and capital lease obligations was \$332,000 and \$517,000 as of September 30, 2017 and December 31, 2016, 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 \$6.7 million and \$5.7 million as of September 30, 2017 and December 31, 2016, respectively. Equipment under capital leases is stated at the present value of minimum lease payments. Depreciation on all property and equipment is calculated on the straight-line method over the shorter of the lease term or estimated useful life of the asset. Computer equipment has useful lives of three to five years, lab equipment has a useful life of five years and contract manufacturing organization equipment has a useful life of five years.

Revenue Recognition

The Company receives payments from government entities under its grants and contracts with the Department of Defense and the United States Department of Health and Human Services. These agreements provide the Company cost reimbursement plus a percentage for certain types of expenditures in return for research and development activities over a contractually defined period. Grant revenues are recognized in the period during which the related costs are incurred, provided that the conditions under which the costs submitted or to be submitted for reimbursement have been met and the Company has only perfunctory obligations outstanding.

The Company had \$10.1 million and \$23.9 million of receivables from the government contracts recorded in other receivables and \$1.5 million and \$4.3 million of unbilled expenses relating to the government contracts recorded in prepaid expenses and other current assets on the balance sheet as of September 30, 2017 and December 31, 2016, respectively. The Company had \$1.4 million and \$2.9 million of accrued expenses for subcontractor fees incurred under the government contracts as of September 30, 2017 and December 31, 2016, respectively.

Recent Accounting Pronouncements

On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it

becomes effective. The new standard is effective for the Company on January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company plans to adopt the standard on a modified retrospective basis at January 1, 2018, with an adjustment for the cumulative effect of all changes recognized in beginning retained earnings. The Company does not expect to record any

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adjustment relating to the Company's licensing and collaboration agreements. The Company continues to assess the impact adoption will have on the government grant revenue contracts.

4. Long-Term Debt

March 2010 City of Ames Forgivable Loan

In March 2010, the Company entered into a \$400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, jointly, as lenders. The project provided the Company with financial assistance to construct new facilities within the Ames city limits.

The project required the Company to create or retain at least 150 full-time positions located in Ames, Iowa by March 10, 2016. The agreement required the Company to enter into a five-year building lease with the option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015, which requirement was met prior to the deadline of March 10, 2015. As of March 10, 2016, the Company had satisfactorily fulfilled all of the above terms of the loan agreement and the loan was forgiven. Accordingly, the entire outstanding loan amount of \$397,000 was derecognized with a corresponding amount recorded in grant revenue for the three months ended March 31, 2016.

5. License and Research Collaboration Agreements

Genentech, a Member of the Roche Group

In October 2014, the Company entered into an exclusive worldwide collaboration and license agreement with Genentech, or the Genentech Agreement, for the development and commercialization of navoximod (GDC-0919), one of the Company's clinical stage IDO pathway inhibitors. The parties also entered into a research collaboration for the discovery of next generation IDO and TDO pathway inhibitors to be developed and commercialized under this agreement. Under the terms of the Genentech Agreement, the Company received a nonrefundable upfront cash payment of \$150.0 million from Genentech in 2014 and is eligible to receive additional milestone payments of up to \$561.0 million upon achieving certain Next Generation Product Development regulatory development, international patent acceptance, country marketing approval, and sales-based milestones. The Company retains the right to exercise an option to co-promote any products for the U.S. market and is also eligible to receive escalating royalty payments on potential commercial sales of products by Genentech.

On June 6, 2017, the Company received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to navoximod with such termination to be effective no later than December 6, 2017. Discussions regarding the termination are ongoing. The Genentech Agreement continues with regards to any Next Generation Products as defined under the Genentech Agreement.

For the three and nine months ended September 30, 2017, the Company recognized license and collaboration revenue under the Genentech Agreement of \$56,000 and \$279,000, respectively, for providing an alliance manager. For the three months ended September 30, 2016, the Company recognized license and collaboration revenue under the Genentech Agreement of \$687,000, including \$486,000 for amounts received as reimbursement for the Company's employees working on the project, and \$201,000 for providing an alliance manager. For the nine months ended September 30, 2016, the Company recognized license and collaboration revenue under the Genentech Agreement of \$2.2 million, including \$1.6 million for amounts received as reimbursement for the Company's employees working on the project, \$502,000 for providing an alliance manager, and \$101,000 for participation in the joint research committee. In accordance with the Company's continuing performance obligation, \$112,000 of the \$150.0 million upfront payment remains deferred as of September 30, 2017 and will be recognized during the remainder of 2017. The upfront payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

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Merck Sharp & Dohme Corp.

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

The Company completed all deliverables under the Merck Agreement in their entirety during the year ended December 31, 2016. For the three months ended September 30, 2016, the Company recognized no revenues under the Merck Agreement. For the nine months ended September 30, 2016, the Company recognized license and collaboration revenues under the Merck Agreement of \$764,000, 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, or the 2000 Plan, and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan, or the 2009 Plan. Following the approval of the 2009 Plan, all options outstanding under the 2000 Plan are effectively included under the 2009 Plan. Under the provisions of the 2009 Plan, the Company may grant the following types of common stock awards:

• Incentive Stock Options

• Nonstatutory Stock Options

• Restricted Stock Awards

• Stock Appreciation Rights

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of September 30, 2017, there were 10,238,220 shares of common stock authorized for the 2009 Plan and 1,094,264 shares remained available for issuance.

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

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



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NewLink Genetics Corporation and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(unaudited)

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 2017 were made pursuant to an "evergreen provision," in accordance with which, on January 1 of each year, from 2012 to (and including) 2019, a number of shares of common stock in an amount equal to 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or such lesser amount of shares (or no shares) approved by the Company's Board of Directors, was added or will be added to the shares reserved under the 2009 Plan.

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

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan, or the Directors' Plan, which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of September 30, 2017, no shares remained available for issuance under the Directors' Plan.

**2010 Employee Stock Purchase Plan**

Under the terms of the Company's 2010 Employee Stock Purchase Plan, or the 2010 Purchase Plan, which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013, an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of September 30, 2017, 120,784 shares remained available for issuance under the 2010 Purchase Plan.

**Share-based Compensation**

Share-based compensation expense for the three months ended September 30, 2017 and 2016 was \$4.4 million and \$3.9 million, respectively, and was \$14.9 million and \$13.1 million, respectively, for nine months ended September 30, 2017 and 2016. Share-based compensation expense is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations.

As of September 30, 2017, the total compensation cost related to nonvested option awards not yet recognized was \$19.9 million and the weighted-average period over which it is expected to be recognized is 2.1 years.

**Stock Options and Performance Stock Options**

The following table summarizes the stock option activity, including options with performance conditions, for the nine months ended September 30, 2017:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	6,278,542	\$ 14.93	5.8
Options granted	1,439,287	11.78	
Options exercised	(108,775 )	8.51	
Options forfeited	(277,443 )	20.13	
Options expired	(17,605 )	42.00	
Outstanding at end of period	7,314,006	\$ 14.15	5.5
Options exercisable at end of period	5,456,602	\$ 12.65	4.4

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.





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 (unaudited)

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted, including those options granted with a market condition, during the nine months ended September 30, 2017:

Risk-free interest rate	1.9% to 2.2%
Expected dividend yield	—%
Expected volatility	68.9% to 73.2%
Expected term (in years)	6.5 to 7.8
Weighted-average grant-date fair value per share	\$7.81

The intrinsic value of options exercised during the nine months ended September 30, 2017 was \$924,164. The fair value of awards vested during the nine months ended September 30, 2017 was \$12.4 million.

During the nine months ended September 30, 2017, the Company's Board of Directors approved and granted 388,144 shares of compensation and equity awards to certain executives with either market or performance conditions. The compensation and equity awards had a weighted average grant date fair value per share of \$6.73. The compensation and equity awards will vest upon the achievement of certain performance conditions. During the nine months ended September 30, 2017, certain conditions were met which resulted in the vesting of 194,070 shares and the recognition of \$1.2 million in stock compensation expense.

#### Restricted Stock and Performance Restricted Stock

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

A summary of the Company's unvested restricted stock, including restricted stock with performance conditions, at September 30, 2017 and changes during the nine months ended September 30, 2017 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	288,964	\$ 34.94
Granted	—	—
Vested	(80,380 )	35.04
Forfeited/cancelled	(27,248 )	33.84
Unvested at end of period	181,336	\$ 35.05

As of September 30, 2017, the total remaining unrecognized compensation cost related to restricted stock was approximately \$4.4 million and is expected to be recognized over a weighted-average period of 1.8 years. As of September 30, 2017, there remains approximately \$6.4 million of unrecognized compensation cost related to the issuance of performance restricted stock. The fair value of awards vested during the nine months ended September 30, 2017 was \$814,000.

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

#### 7. Income Taxes

For the three and nine months ended September 30, 2017, the Company recorded an income tax benefit of \$119,000 and \$429,000, respectively. For the three and nine months ended September 30, 2016, the Company recorded an

income tax benefit of \$1.3 million and \$5.0 million, respectively. The income tax benefit for the three and nine months ended September 30, 2017 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the limited potential to carry back losses to 2015 and the net loss generated by NewLink's foreign subsidiary. Income tax benefit for the three and nine months ended September 30, 2016 differs from the amount that would be expected after applying the statutory U.S.

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federal income tax rate primarily due to the ability to carry back losses to 2014 and the net loss generated by the NewLink's foreign subsidiary.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of September 30, 2017 and December 31, 2016, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of \$843,000 as of September 30, 2017 recorded within Accrued Expenses in the condensed consolidated balance sheet, which includes the accrual of interest and penalties. The Company does not expect the amount to change significantly within the next 12 months.

#### 8. Net Loss per Common Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Loss attributable to common stockholders	\$ (20,626 )	\$ (15,540 )	\$ (58,265 )	\$ (71,649 )
Basic and diluted weighted-average shares outstanding	29,939,823	28,983,561	29,462,226	28,911,042
Basic and diluted loss per share	\$ (0.69 )	\$ (0.54 )	\$ (1.98 )	\$ (2.48 )

All common stock equivalents are excluded from the computation of diluted loss per share during periods in which losses are reported since the result would be anti-dilutive. As of September 30, 2017, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 7,314,006 and 181,336, respectively. As of September 30, 2016, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 6,453,331 and 307,079, respectively.

#### 9. Restructuring Charges

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

In July 2017, the Company undertook an organizational realignment to refocus its clinical development efforts and align the Company's resources to focus on the Company's highest value opportunities. The Company's restructuring activities included a reduction of its workforce by approximately 50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Restructuring charges recorded during the three and nine months ended September 30, 2017 included \$1.7 million in employee severance

cost, which is comprised of one-time employee termination benefits and certain expenses related to contractual termination benefits for employees with pre-existing severance arrangements.

In May 2016, the Company announced that its Phase 3 clinical trial Immunotherapy for Pancreatic REsectable cancer Study, or IMPRESS, of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint and in order to

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reduce costs associated with algenpantucel-L and the HyperAcute® Cellular Immunotherapy platform technology, the Company's management adopted a restructuring plan in May 2016 which included a reduction in the Company's workforce; the exit or reduction of certain leased facilities; and the renegotiation or termination of contracts with certain third parties. As a result of the restructuring, the Company also impaired fixed assets which management determined had no or limited future use. The fair value of impaired fixed assets was determined based on management's estimate of market resale value. Restructuring charges recorded during 2016 were \$12.3 million, of which \$500,000 is included within general and administrative expenses and \$11.8 million is included within the research and development expenses in the condensed consolidated statement of operations. Included in the \$12.3 million of charges is non-cash asset impairment charges of \$4.0 million. No additional charges related to the 2016 restructuring were recorded during the three and nine months ended September 30, 2017 and all amounts accrued as of December 31, 2016 were paid by the end of the first quarter of 2017.

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

	Employee Severance Cost	Total
Balance as of December 31, 2016	\$ 42	\$42
Expensed	1,695	1,695
Cash Payments	1,085	1,085
Balance as of September 30, 2017	\$ 652	\$652

The majority of the charges are expected to be paid by the end of the year.

**10. Commitments and Contingencies**

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

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint which asserts claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase II and III trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs do not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they seek 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. On April 27, 2017, the Court granted the parties' request for leave to brief a motion to dismiss the amended complaint, and ordered the parties to file a stipulation and proposed order setting forth a schedule for the briefing of that motion. On May 15, 2017, the Court ordered the following briefing schedule: motion to dismiss due July 14, 2017, opposition due September 12, 2017, and reply due September 26, 2017. The Defendants filed a motion to dismiss on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. The Company disputes the claims in

the Securities Action and intends to defend against them vigorously.

On or about April 26, 2017, Ronald Morrow filed a shareholder derivative lawsuit on behalf of the Company in the United States District Court for the Southern District of New York, or the Court, against the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Medical Officer and President Nicholas Vahanian, and Company directors Thomas A. Raffin, Joseph Saluri, Ernest J. Talarico, III, Paul R. Edick, Paolo Pucci, and Lota S. Zoth, or collectively, the Morrow Defendants, captioned Morrow v. Link., et al., Case 1:17-cv-03039, or the Morrow Action. The complaint alleges that the Morrow Defendants caused the Company to issue false statements in its 2016 proxy statement regarding risk management and compensation matters in violation

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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 II and III trials and efficacy of the product candidate algenpantucel-L, awarded themselves excessive compensation, engaged in illegal insider trading, and grossly mismanaged the Company. The plaintiff does not quantify any alleged damages in the complaint but seeks restitution for damages to the Company, attorneys' fees, costs, and expenses, as well as an order directing that proposals for strengthening board oversight be put to a vote of the Company's shareholders. The language for such proposals is not specified in the complaint. The plaintiff also contemporaneously filed a statement of relatedness, informing the Court that the Morrow Action is related to Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545. On May 19, 2017, the plaintiff dismissed the Morrow Action without prejudice. Also on May 19, 2017, plaintiffs' counsel in the Morrow Action filed a new shareholder derivative complaint that is substantively identical to the Morrow Action, except that the plaintiff is Rickey Ely. The latter action is captioned Ely v. Link, et al., Case 17-cv-3799, or the Ely Action. By agreement of the parties and order dated June 26, 2017, the Court temporarily stayed the Ely Action until the Securities Action is dismissed or otherwise resolved. Under the terms of the stay, the plaintiff in the Ely Action will be provided with any discovery that is provided in the Securities Action, and given an opportunity to participate in any mediation or settlement efforts in the Securities Action. The Company disputes the claims in the Ely Action and intends to defend against them vigorously.

11. Subsequent Events

On October 6, 2017, the Company sold 5,750,000 shares of its common stock for total proceeds of \$55.2 million, net of offering expenses of \$3.7 million. Net proceeds from the offering will be used to further advance its pipeline of product candidates, including the continued clinical development of indoximod, and for working capital and other general corporate purposes.



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### 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,” “po” 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 clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our 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, 2016. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

#### Overview

We are a late clinical-stage immuno-oncology company focused on discovering and developing novel immunotherapeutic products for the treatment of patients with cancer. We are committed to developing our pipeline of small-molecule and biologic immuno-oncology product candidates intended to treat a wide range of oncology indications. Our leading small-molecule product candidates currently in clinical development target the indoleamine-2, 3-dioxygenase, or IDO, pathway, which is one of the key pathways for cancer immune escape. These product candidates, indoximod, NLG802 and navoximod (formerly GDC-0919), are IDO pathway inhibitors with mechanisms of action that center around breaking the immune system’s tolerance to cancer. Additional clinical-stage product candidates in our pipeline include two product candidates that utilize our HyperAcute® Cellular Immunotherapy technology and two small molecules we acquired in 2017 from Cerulean Pharmaceuticals. The HyperAcute candidates, tergenpumatulcel-L and dorgenmeltucel-L, are in Phase 2 clinical trials for patients with advanced lung cancer and melanoma, respectively. The two small molecules, CRLX101 and CRLX301, are being evaluated in early clinical development for patients with advanced solid malignancies. Additional clinical trials with these product candidates are under consideration, pending the outcome of the current studies and the availability of resources.

We believe that immune system failure is a fundamental reason for the inability of the human body to successfully fight cancer cells. Research into the inability of the immune system to respond to cancerous tumors indicates that tumors can induce the human immune system to tolerate the existence of the tumor. This immune tolerance and suppression represents a major barrier to successful treatment of cancer and is a significant target for new therapeutics.

Scientific understanding of the process leading to immune tolerance, while moving rapidly, is still in its early stages. We believe IDO is part of a system that may be used by some tumors as a mechanism to evade the immune system. In cancer, the IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumors to avoid immune response. The IDO pathway is expressed in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, whereby this pathway promotes peripheral tolerance to tumor associated antigens, or TAAs. When hijacked by developing cancers in this manner, the IDO pathway may facilitate the survival, growth, invasion and metastasis of malignant cells whose expression of TAAs might otherwise be recognized and attacked by the immune system.

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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 break-down product of tryptophan metabolism, kynurenine, is understood to suppress the activation of T-cells. Direct enzymatic inhibitors such as navoximod and peer molecules of other companies inhibit the IDO enzyme directly and thereby prevents the metabolism of tryptophan into kynurenine. We believe that indoximod has a different mechanism of action from such direct enzymatic inhibitors and acts in part directly on T-cells bypassing the effects of IDO activity. Indoximod may also “mimic” tryptophan and signal the activation of antitumor T-cells in a local microenvironment where IDO is active. Indoximod is therefore understood to return the immune system to a more active state.

While traditional chemotherapy places substantial stress on tumor-induced immune tolerance, this effect often dissipates following the end of chemotherapy treatment. Cytotoxic chemotherapy appears to mitigate immune tolerance in several ways: (1) dying tumor cells release waves of TAAs for processing and presentation, (2) many chemotherapeutic regimens induce a period of transient lymphopenia and homeostatic recovery during which T-cells may become more susceptible to breaking tolerance, and (3) certain regimens can transiently deplete or inactivate tumor-protective T-regulatory cells. However, most chemotherapeutic agents do not appear to trigger a protective immune response against established tumors, as many tumors rapidly re-establish tolerance following each cycle of chemotherapy. We believe a potential portion of this mechanism underlying these phenomena is IDO expression by APCs in tumor-draining lymph nodes, which triggers an immunosuppression and immune tolerance to cancer. Preclinical and, increasingly, clinical data suggest that IDO pathway inhibitors may enhance the anti-tumor effects of other immunotherapies, chemotherapies and radiation, when used in combination.

The ability to eliminate the protective IDO mechanism by administering IDO pathway inhibitor drugs may provide a therapeutic window in which to break tolerance in some tumors and reverse the inhibition of immune cells.

### IDO Pathway Inhibitor Clinical Development

#### Indoximod

Indoximod, our lead IDO pathway inhibitor, has a differentiated mechanism of action from other drugs in the class of IDO inhibitors and is currently in Phase 2 clinical development in combination with other cancer therapeutics for patients with melanoma, pancreatic cancer and acute myeloid leukemia. We intend to launch a pivotal Phase 3 clinical trial in the first quarter of 2018 for patients with advanced melanoma, and we expect to substantially complete enrollment by the end of 2018. Indoximod has been studied in more than 700 patients to date and has been generally well-tolerated, both as a single agent and in combination with PD-1 checkpoint inhibitors, various chemotherapy agents and a cancer vaccine. Primary tumor types being explored in clinical trials include melanoma, pancreatic cancer and acute myeloid leukemia. We believe there may be additional opportunities for a broad set of cancer indications. We expect data from our Phase 2 trial for patients with pancreatic cancer in the first half of 2018, completion of our Phase 2 trial for patients with acute myeloid leukemia in the second half of 2018 and completion of our Phase 2 trial for patients with advanced melanoma in 2018. A summary of these key trials is set forth in the table below.

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Our planned pivotal clinical trial in advanced melanoma is a Phase 3 investigation of indoximod in combination with a checkpoint inhibitor for advanced unresectable and metastatic melanoma compared to the checkpoint inhibitor alone. The trial will have a 1:1 randomized, double blind, placebo controlled design. Participating investigators will be allowed to prescribe either of the U.S. Food and Drug Administration, or FDA, approved PD-1 checkpoint inhibitors, KEYTRUDA® (pembrolizumab) or OPDIVO® (nivolumab), and patients will then be randomized to receive indoximod or placebo in conjunction with the checkpoint inhibitor. The trial will have co-primary endpoints by Response Evaluation in Solid Tumors, or RECIST, criteria of progression free survival and overall survival. The planned enrollment is approximately 600 patients.

A U.S. patent covering salt and prodrug formulations of indoximod was issued to us on August 15, 2017 providing exclusivity into 2036. We are pursuing international patent coverage for these formulations. We intend to use the improved salt formulation of indoximod in our planned Phase 3 clinical trial. The required clinical safety testing for this new formulation is being addressed in an ongoing trial in patients with acute myeloid leukemia and will also be addressed in the pivotal Phase 3 clinical trial in patients with advanced melanoma. This plan was discussed with the FDA during a Type B meeting, and the FDA agreed that the plan would likely satisfy the requirement for a clinical bridge. If the results of any of these clinical trials raise meaningful concerns about clinical safety, the time and expense required to initiate and complete our Phase 3 clinical trial would likely increase.

### NLG802

NLG802 is a prodrug of indoximod. NLG802 is intended to increase bioavailability and exposure to indoximod above the levels currently achievable by direct oral administration of the original formulation of indoximod. We filed an Investigational New Drug application, or IND, with the 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.

### Navoximod (formerly GDC-0919)

Navoximod, a direct enzymatic inhibitor, was previously in clinical development as part of our collaboration with Genentech, Inc., a member of the Roche Group, or Genentech. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, or the Genentech Agreement. The Genentech Agreement provided for the development and commercialization of navoximod. In addition, under the Genentech Agreement, we conducted a two-year pre-clinical research program with Genentech to discover novel next generation IDO/TDO (tryptophan-2, 3-dioxygenase) inhibitors. The research program ended in November 2016, but our collaboration with Genentech continues with respect to next generation IDO/TDO inhibitors identified through the research program.

On June 6, 2017, we received a formal notice of Genentech's intent to terminate the Genentech Agreement with respect to navoximod with such termination to be effective no later than December 6, 2017. Discussions regarding the termination are ongoing. The Genentech Agreement will continue with regards to any Next Generation Products and/or Subsequent Products as defined under the Genentech Agreement.

### PTEN

We also have an early discovery program focused on Phosphatase and Tensin Homolog in Chromosome 10, or PTEN. Recent advances in the characterization of the IDO pathway have suggested that IDO activates a subset of PD-1-dependent regulatory T-cells, or Tregs, that are potentially immunosuppressive. Evidence suggests these Treg cells mediate systemic immunosuppression against tumor-associated antigens and that the function of PTEN may be important to maintaining the suppressive character of these cells. Based on data from preclinical animal models, we believe that the efficacy of PTEN inhibitors might be enhanced when combined with different standard-of-care therapeutic approaches such as chemotherapy and radiotherapy, as well as with IDO pathway inhibitors such as indoximod.

In March 2016, we entered into an exclusive, worldwide license agreement with Augusta University Research Institute, or AURI, related to PTEN inhibitor products. Under the terms of such agreement, or the AURI PTEN License Agreement, we paid an upfront payment to AURI of \$1.0 million and we are obligated to pay AURI potential milestone payments in an aggregate amount up to approximately \$4.3 million and royalties at a single-digit or less

percentage of net sales of royalty-bearing products, or PTEN inhibitor products that are covered by licensed patents or certain of our patents or that were researched or developed using licensed technology. In addition, if we grant a sublicense under the license granted by AURI or we grant a license to certain of our patents that cover royalty-bearing products, we must pay to AURI a percentage of certain specified consideration that we receive from the sublicensee or licensee.

Ebola Vaccine Candidate

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In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our rVSVΔG-ZEBOV GP vaccine product candidate and other aspects of our vaccine technology. The rVSVΔG-ZEBOV GP vaccine product candidate was originally developed by the Public Health Agency of Canada, or PHAC, and is designed to utilize the rVSV vector to induce immunity against Ebola virus when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. Under the Merck Agreement, we received an upfront payment of \$30.0 million in October 2014, and in February 2015 we received a milestone payment of \$20.0 million. We have the potential to earn royalties on sales of the vaccine in certain countries, if the vaccine is approved and if Merck successfully commercializes it. rVSVΔG-ZEBOV GP is also eligible to receive a priority review voucher and we are entitled to a portion of the value of the voucher if it is granted. In addition to milestone payments from Merck, we were awarded contracts for development of the rVSVΔG-ZEBOV GP from the U.S. BioMedical Advanced Research & Development Authority and the Defense Threat Reduction Agency totaling \$52.1 million during 2016 and \$67.0 million during 2014 and 2015, for total awards of \$119.1 million.

### Recent Developments

#### Collaboration with AstraZeneca

On September 25, 2017, we announced that we have entered into a clinical collaboration agreement with AstraZeneca to evaluate the combination of indoximod and durvalumab, AstraZeneca's anti-PD-L1 monoclonal antibody, along with standard of care chemotherapy for patients with metastatic pancreatic cancer. We and AstraZeneca have agreed to initiate a randomized, placebo-controlled, Phase 2 clinical trial with the primary objective to evaluate the efficacy and safety of the immuno-oncology-based indoximod/durvalumab combination compared to gemcitabine/ABRAXANE alone. Some patients will be enrolled into a smaller cohort evaluating the combination of durvalumab with gemcitabine/ABRAXANE. From the date of our agreement with AstraZeneca and for 90 days after the completion of such combination study, we may not conduct a clinical trial involving the combination of indoximod and any compound that targets PD-1 or PD-L1 (other than durvalumab) for the metastatic pancreatic cancer indication, and AstraZeneca may not conduct a clinical trial involving the combination of durvalumab and any IDO pathway inhibitor (other than indoximod) for the metastatic pancreatic cancer indication. The Phase 2 clinical trial will be funded equally by both companies, with us serving as the study sponsor. Our share of the aggregate expense of the trial is not expected to have a material effect on our financial position. We expect to begin enrolling patients in the first quarter of 2018.

The market opportunity for the treatment of pancreatic cancer is substantial. Approximately 54,000 new cases of pancreatic cancer in the United States will be diagnosed in 2017 according to the National Cancer Institute, or NCI, and a little over 43,000 people will die of the disease this year. Pancreatic cancer is difficult to detect in its early stages and approximately 52% of all pancreatic cancers are metastatic, or advanced, in nature and are associated with a poor prognosis. The 5-year survival rate for pancreatic cancer overall is only 8.2%, and drops to a low of 2.7% for individuals whose pancreatic cancer has metastasized to farther regions of the body.

#### Updated Phase 2 Data for Patients with Advanced Melanoma

On September 7, 2017, we announced updated data from the ongoing Phase 2 NLG2103 trial of indoximod in combination with the PD-1 pathway inhibitor, KEYTRUDA (pembrolizumab). These data were highlighted in an oral presentation at the Third International Cancer Immunotherapy conference in Frankfurt/Mainz, Germany, on September 9, 2017 by Yousef Zakharia, M.D., Assistant Professor of Medicine, Division of Hematology, Oncology and Blood & Marrow Transplantation at the University of Iowa and Holden Comprehensive Cancer Center. NLG2103 is a Phase 2 trial evaluating the addition of indoximod to the standard of care checkpoint inhibitors approved for patients with advanced melanoma (pembrolizumab, ipilimumab, or nivolumab). The interim data represent a cohort of approximately 60 evaluable patients who received indoximod in combination with pembrolizumab. Evaluable patients were defined as those having at least one on-treatment imaging study. The primary outcome measure of the trial is objective response rate, or ORR, and secondary outcome measures include disease control rate and evaluation of safety and tolerability.

The data presented showed an improvement over previously reported results for the same 51 patients with cutaneous, mucosal and melanoma of unknown primary origin first presented at the American Association for Cancer Research

Annual Meeting 2017 for both the complete response rate, or CR, and the ORR for patients who received indoximod in combination with pembrolizumab. The data showed improvement in CR to 20% (10/51 patients) compared to the previously reported CR of 12% (6/51 patients). The Progression-Free Survival, or PFS, by RECIST criteria was 56% at one year with median PFS of 12.9 months.

#### Restructuring Charges

In July 2017, we undertook an organizational realignment to refocus our clinical development efforts and align our resources to focus on our highest value opportunities. The restructuring activities included a reduction of our workforce by approximately

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50%, which consisted primarily of clinical and research and development staff, as well as stopping additional research on the Zika virus. Refer to Note 9 for more information.

### Corporate Information

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

We incurred a net loss of \$58.3 million for the nine months ended September 30, 2017. 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, 2016, discusses our most critical accounting policies. Since December 31, 2016, there have been no material changes in the critical accounting policies discussed in our 2016 Annual Report.

### Recent Accounting Pronouncements

We do not believe that any recently issued effective pronouncements, or pronouncements issued but not yet effective, if adopted, would have a material effect on the accompanying financial statements.

## Results of Operations

### Comparison of the Three Months Ended September 30, 2017 and 2016

**Revenues.** Revenues for the three months ended September 30, 2017 were \$5.5 million, a decrease of \$9.8 million from \$15.3 million for the same period in 2016. The decrease in revenue was due to a decrease in grant revenue of \$9.1 million, primarily due to a decrease in billings under the government grant contracts, and a decrease of \$785,000 in licensing revenue. Licensing revenues declined due to lower revenues recognized under the Genentech Agreement in the three months ended September 30, 2017. For the three months ended September 30, 2017 and 2016, revenues recognized under the Genentech Agreement were \$56,000 and \$687,000, respectively.

**Research and Development Expenses.** Research and development expenses for the three months ended September 30, 2017 were \$18.5 million, a decrease of \$6.0 million from \$24.5 million for the same period in 2016. The decrease was due primarily to a \$6.2 million decline in contract research and manufacturing spend, a \$500,000 decrease in personnel-related spend, and a \$530,000 decline in clinical trial and other supplies, offset by an increase of \$630,000 in one-time restructuring expense incurred for employee severance during the third quarter of 2017, an increase of \$370,000 in legal and consulting spend, and an increase of \$230,000 in stock compensation expense.

**General and Administrative Expenses.** General and administrative expenses for the three months ended September 30, 2017 were \$7.9 million, an increase of \$200,000 from \$7.7 million for the same period in 2016. The increase was due to a one-time restructuring expense incurred for employee severance during the third quarter of 2017 of \$1.1 million, an increase of \$370,000 for supplies and other expenses, and an increase in stock compensation expense of \$260,000 offset by a decline of \$1.1 million in personnel-related spend, and a decline of \$430,000 in consulting and legal fees.

**Income Tax Benefit.** The income tax benefit for the three months ended September 30, 2017 was \$119,000, compared to an income tax benefit of \$1.3 million for the same period in 2016. The change of \$1.2 million is primarily due to



the limited ability to carry 2017 losses back to 2015 compared to the larger benefit generated by the ability to carry 2016 losses back to 2014. The effective tax rate differs between periods primarily due to the change in the net loss generated by our foreign subsidiary and

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the ability to carry losses from 2017 and 2016 back to prior years. The full benefit in 2017 to be carried back to prior years is limited to the loss available in 2015.

**Net Loss.** The net loss for the three months ended September 30, 2017 was \$20.6 million compared to net loss of \$15.5 million for the same period in 2016. The basic and diluted weighted average common shares outstanding for the three months ended September 30, 2017 were 29,939,823, resulting in a basic and diluted loss per share of \$0.69. For the three months ended September 30, 2016, the basic and diluted weighted average common shares outstanding were 28,983,561, resulting in basic and diluted loss per share of \$0.54.

**Comparison of the Nine Months Ended September 30, 2017 and 2016**

**Revenues.** Revenues for the nine months ended September 30, 2017 were \$18.6 million, a decrease of \$4.5 million from \$23.1 million for the same period in 2016. The decrease in revenue was due to a decrease in grant revenue of \$1.8 million, primarily due to a decrease in billings under the government grant contracts, and a decrease of \$2.7 million in licensing revenue. Licensing revenues declined primarily due to lower revenues recognized under the Genentech and Merck Agreements in the nine months ended September 30, 2017. For the nine months ended September 30, 2017 and 2016, revenues recognized under the Genentech Agreement were \$279,000 and \$2.2 million, respectively. No revenues were recognized under the Merck Agreement for the nine months ended September 30, 2017 compared to revenues of \$764,000 for the nine months ended September 30, 2016.

**Research and Development Expenses.** Research and development expenses for the nine months ended September 30, 2017 were \$52.4 million, a decrease of \$21.4 million from \$73.8 million for the same period in 2016. The decrease was primarily due to a decrease of \$11.2 million in restructuring charges. During the nine months ended September 30, 2017 we incurred restructuring charges of \$630,000 for employee severance costs compared to restructuring charges of \$11.8 million for contract termination fees of \$6.5 million, a fixed asset impairment charge of \$4.0 million and employee severance of \$1.3 million during the comparable period in 2016. The remainder of the change year over year is due to a decline in clinical trial spend of \$4.9 million, a decrease in supplies and other expenses of \$3.5 million, a decrease in personnel-related expense of \$2.9 million, and a decrease in licensing fees of \$600,000. These reductions in spend were offset by an increase in stock compensation expense of \$1.1 million, an increase in manufacturing spend of \$310,000, and an increase in legal and consulting fees of \$300,000.

**General and Administrative Expenses.** General and administrative expenses for the nine months ended September 30, 2017 were \$25.0 million, a decrease of \$1.0 million from \$26.0 million for the same period in 2016. The decrease was due primarily to a reduction in personnel-related spend of \$2.3 million and a reduction in legal and consulting of \$680,000. These decreases were offset by an increase in stock compensation expense of \$760,000, an increase in supplies and other expenses of \$650,000, and an increase in restructuring charges of \$570,000 for employee severance costs.

**Income Tax Benefit.** The income tax benefit for the nine months ended September 30, 2017 was \$429,000, compared to income tax benefit of \$5.0 million for the same period in 2016. The change of \$4.6 million is primarily due to the limited ability to carry 2017 losses back to 2015 compared to the larger benefit generated by the ability to carry 2016 losses back to 2014. The effective tax rate differs between periods primarily due to the change in the net loss generated by our foreign subsidiary and the ability to carry losses from 2017 and 2016 back to prior years and limitations on the amount available to be used in prior years.

**Net Loss.** The net loss for the nine months ended September 30, 2017 was \$58.3 million compared to net loss of \$71.6 million for the same period in 2016. The basic and diluted weighted average common shares outstanding for the nine months ended September 30, 2017 were 29,462,226, resulting in a basic and diluted loss per share of \$1.98. For the nine months ended September 30, 2016, the basic and diluted weighted average common shares outstanding were 28,911,042, resulting in basic and diluted loss per share of \$2.48.

## Liquidity and Capital Resources

As of September 30, 2017, we had cash and cash equivalents of \$120.7 million. We have funded our operations principally through the private placement of equity securities and public offerings of common stock. To date, we have raised aggregate proceeds, net of offering costs, of \$76.3 million from the issuance of convertible preferred stock prior

to our IPO, and \$145.3 million in net proceeds through our IPO and other public follow-on offerings. Additionally, on November 29, 2016, we entered into a Sales Agreement with Cantor Fitzgerald & Co., or Cantor, under which we may sell up to \$40.0 million of our common stock in one or more placements at prevailing market prices in an ATM offering. We launched this ATM in June 2017. During the three months ended September 30, 2017, we sold 1,940,656 shares of common stock under this ATM, with aggregate net proceeds of \$19.3 million after commissions of \$398,000 paid to Cantor as the placement agent and other expenses of \$163,000. Also subsequent to September 30, 2017, we sold 5,750,000 shares of common stock in a public offering for aggregate net proceeds of \$55.2 million after underwriters' discounts, commissions and other expenses of \$3.7 million.

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

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

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

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

We believe that our cash and cash equivalents on hand and the proceeds from our recent public offering will be sufficient to fund our planned operations into the second quarter of 2020.

**Cash Flows**

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

**Sources and Uses of Cash and Cash Equivalents**

(in thousands)

	Nine Months Ended	
	September 30,	
	2017	2016
Net cash used in operating activities	\$(31,070)	\$(48,933)
Net cash provided by investing activities	142	111
Net cash provided by financing activities	20,140	1,478
Net decrease in cash and cash equivalents	\$(10,788)	\$(47,344)

For the nine months ended September 30, 2017 and 2016, we used cash of \$31.1 million and \$48.9 million, respectively, for our operating activities. For the nine months ended September 30, 2017, the sources and uses of cash in this period primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. The decrease in cash used in operating activities was primarily due to the decrease in research and development activity offset by changes in working capital and a decrease in revenues for the nine months ended September 30, 2017 as compared to revenues for the nine months ended September 30, 2016.

For the nine months ended September 30, 2017 and 2016, our investing activities provided cash of \$142,000 and \$111,000, respectively. The cash provided by investing activities during the nine months ended September 30, 2017

was due to proceeds received from sales of property and equipment of \$185,000 offset by \$43,000 in purchases of property and equipment. The cash

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provided by investing activities during the nine months ended September 30, 2016 was due to maturity of certificates of deposit for \$2.2 million offset by \$2.1 million in purchases of property and equipment.

For the nine months ended September 30, 2017 and 2016, our financing activities provided cash of \$20.1 million and \$1.5 million, respectively. The cash provided by financing activities in the nine months ended September 30, 2017 was due to the issuance of common stock for net proceeds of \$20.6 million offset by net payments on long-term obligations and notes payable of \$185,000 and repurchases of common stock of \$260,000. The cash provided by financing activities in the nine months ended September 30, 2016 was primarily due to the sale and issuance of common stock for net proceeds of \$1.7 million, offset by net payments on long-term obligations and notes payable of \$197,000, and repurchase of common stock of \$13,000.

### Contractual Obligations and Commitments

There are no material changes to our contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

### Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

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

We are exposed to market risk related to changes in interest rates. As of September 30, 2017 and December 31, 2016, we had cash and cash equivalents and certificates of deposit of \$120.7 million and \$131.5 million, respectively, consisting primarily of money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

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

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of September 30, 2017. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of September 30, 2017, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and to provide reasonable assurance that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosures.

### Changes in Internal Control over Financial Reporting

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



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PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

RISK FACTORS

Investing in our common stock involves significant risks, some of which are described below. In evaluating our business, investors should carefully consider the following risk factors. These risk factors contain, in addition to historical information, forward-looking statements that involve substantial risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Business Risks

Risks Relating to Clinical Development and Commercialization of Our Product Candidates

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

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

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities abroad. The number and design of clinical trials that will be required varies depending on the product candidate, the condition being evaluated, the trial results and regulations applicable to any particular product candidate. Any inability to successfully complete preclinical and clinical development could result in additional costs to us.

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in later-stage clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

We are heavily dependent on the success of the clinical development of indoximod, and if we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize indoximod, our business, financial condition and results of operations would be harmed. The indoximod clinical development program currently encompasses a number of Phase 1 and 2 combination trials across multiple cancer indications. In addition, we have announced that we intend to begin a large-scale randomized pivotal Phase 3 clinical trial of Indoximod in combination with PD-1 antibody for patients with advanced melanoma designed to support a new drug application. 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





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trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing Investigational New Drug applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

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

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

- we may experience delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;
- regulators or institutional review boards may not authorize us to commence a clinical trial;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- we may need to reformulate or change the dosing of our product candidates;
- our clinical trials may have slower than expected patient enrollment or lack of a sufficient number of patients that meet their enrollment criteria;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- we may experience difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our clinical trial protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials;
- our third-party contractors, including those manufacturing our product candidates or components of ingredients thereof or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- the supply or quality of raw materials or manufactured product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
-

we may experience governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;

• enrollment in and conduct of our clinical trials may be adversely affected by the regulatory approval of competing agents in this class, competition with ongoing clinical trials or scheduling conflicts with participating clinicians; and  
• we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

In addition, we rely on academic institutions, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other

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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 Phase 3 clinical trials evaluating potentially competing IDO pathway inhibitors in clinical settings similar to our clinical trials;
- 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.

We have experienced difficulties enrolling patients in certain of our smaller clinical trials due to lack of referrals and may experience similar difficulties in the future. If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business.

In addition, the inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events for reasons that may not be related to the product candidate we are testing or, in those trials where our product candidate is being tested in combination with one or more other therapies, for reasons that may be attributable to such other therapies, but which can nevertheless negatively affect clinical trial results.

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

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



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

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

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

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

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

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

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

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

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

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

Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice, or GCP, requirements, or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and Institutional Review Boards at the medical institutions where the clinical trials are conducted. In

addition, clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, requirements and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

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- 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, navoximod, and other product candidates could take significantly longer to gain regulatory approval than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating their commercialization.

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

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

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

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

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

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





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Even if ultimately approved, indoximod, navoximod, NLG802, 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 are 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, including to co-promote next generation IDO/TDO inhibitors in the United States, under the Genentech Agreement.

We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and



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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. On July 28, 2017, we announced that Dr. Nicholas N. Vahanian will be on a temporary leave of absence and that during his absence, other members of the management team will assume his duties. The long-term loss of services of key executives might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. Additionally, our only significant facility is located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

### **Risks Relating to Manufacturing Activities**

We rely on third-party manufacturers to produce our preclinical and clinical product candidate supplies and we intend to rely on third parties to produce commercial supplies of any product candidates that may be approved in the future. Any failure by a third-party manufacturer to produce supplies for us may delay or impair our ability to complete our clinical trials or commercialize our product candidates.

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

Any prolonged delay or interruption in the operations of our current or future contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product. A number of factors could cause interruptions, including the inability of a supplier to provide raw materials, equipment malfunctions or failures, damage to a facility due to natural disasters, changes in international or U.S. regulatory requirements or standards that require modifications to our manufacturing processes, action by regulatory authorities or by us that results in the halting or slowdown of production of components or finished product due to regulatory issues, a contract manufacturer going out of business or failing to produce product as contractually required or other similar factors. Because manufacturing processes are highly complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of product candidates could delay our clinical trials, increase our costs, damage our

reputation and cause us to lose revenue and market share if we are unable to meet market demand for any products that are approved for sale on a timely basis.

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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.

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

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

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

Our primary facility is located in Ames, Iowa, which is susceptible to floods and tornados, and our facility is therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business insurance (real, personal and business income) of nearly \$12.1 million in the aggregate, but this policy does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

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

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

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

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

The research, 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.

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There can be no assurance that clinical trials for any of our product candidates currently under development will be completed successfully or within any specified time period, if at all. Further, there can also be no assurance that such testing will show any product to be safe, pure, potent or effective. We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. In addition, regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate.

Even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including:

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

The FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of new biologic and pharmaceutical products through lengthy and detailed preclinical and clinical testing procedures, sampling activities and other costly and time-consuming compliance procedures. Clinical trials are vigorously regulated and must meet requirements for FDA review and oversight and requirements under GCP guidelines. A new drug may not be marketed in the United States until the FDA has approved it. There can be no assurance that we will not encounter delays or rejections or that the FDA will not make policy changes during the period of product development and FDA regulatory review of each submitted BLA and NDA. A delay in obtaining, or failure to obtain, such approvals would have a material adverse effect on our business, financial condition and results of operations.

Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record-keeping and reporting of adverse experiences and other information. In addition, we would be required to comply with federal and state anti-kickback and other healthcare fraud and abuse laws that pertain to the marketing of pharmaceuticals. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Noncompliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or

by the FDA. Foreign regulatory authorities could also require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses including, but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistleblowing. Any actual or alleged failure to comply with any regulation applicable to our business or any

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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. 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 health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.

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

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

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing; 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 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, marketing 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 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 exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions 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 exemption 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 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.

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Private parties may initiate qui tam whistleblower lawsuits against any person or entity under the 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, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization on covered entities, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information.

The federal Food, Drug and Cosmetic Act, or FDCA, prohibits, among other things, the adulteration or misbranding of drugs and medical devices.

The federal Physician Payments Sunshine Act, and its implementing regulations require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services 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; 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 requires 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 includes a budget neutrality provision that requires 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 to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on

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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 be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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, or 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. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017 in May 2017. More recently, the Senate Republicans proposed multiple bills to repeal or repeal and replace portions of the ACA. Although none of these measure has successfully passed Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA. In addition, there has been particular and increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices in recent years, particularly with respect to drugs that have been subject to relatively large price increases over relatively short time periods. There have been several recent U.S. Congressional inquiries and proposed bills 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. 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.

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.

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

In addition, given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any



such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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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.

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

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

### Financial Risks

Despite our profitable fiscal year ended December 31, 2014, we have a history of net losses. We incurred a net loss for the years ended December 31, 2015 and 2016 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. Any future milestone payments under the Genentech Agreement depend on our achievement of specific milestones, and any royalties depend on successful commercialization of licensed products. The potential milestone and royalty payments under the Genentech Agreement are highly uncertain and dependent on many factors outside of our control related to possible future clinical trials and commercialization.

We do not expect any milestone or royalty payments under these or other agreements, if any, to be sufficient to make us profitable in future years. As a result of these and other factors, we incurred a net loss of \$85.2 million for the year ended December 31, 2016 and we do not expect to be profitable for the foreseeable future. If we had not received the upfront payments under the Genentech Agreement and the Merck Agreement, we would have incurred a net loss for the year ended December 31, 2014. We anticipate that we will continue to incur operating losses over the next several years as we expand both our commercialization activities and our discovery and research activities.

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

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

Development of our product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities, either internally or through collaborations with third parties. Our future capital requirements will depend on many factors, including, among others:

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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 into the second quarter of 2020. However, our operating plan may change as a result of factors currently unknown to us.

There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from approximately \$200,000 to \$4.3 million under our license agreements (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

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

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



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

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

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

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

For the nine months ended September 30, 2017 we have a tax benefit due to our ability to carry net operating losses back to the year ended December 31, 2015 which was subject to federal income taxes in the United States. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates, our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

### **Risks Relating to Competition**

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

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

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

We 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.

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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 may also be adversely effected by the clinical trial results of our competitors. For example, if a competitor announces inconclusive or negative clinical trial results with respect to an IDO pathway inhibitor, expectations about IDO pathway inhibitors may be generally impacted and we may experience difficulty in enrolling patients in our indoximod trials. If we obtain regulatory approval and launch commercial sales of our product candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience.

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

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

Research and discoveries by others may result in breakthroughs that render indoximod, navoximod, HyperAcute Cellular Immunotherapy 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 infectious disease product candidates face significant competition for United States government funding for both development and procurement of vaccines against infectious diseases, medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Public and private biopharmaceutical companies, academic institutions, government agencies, private research organizations and public research organizations are conducting research and filing patents toward commercialization of products.

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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 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 and Genentech is responsible for clinical trials that it conducted on navoximod prior to terminating its rights to navoximod and for any clinical trials that it may conduct on next generation IDO/TDO inhibitor products, 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 Genentech and Merck for the development of the product candidates that are the subject of the Genentech Agreement and the Merck Agreement. If either company does not succeed in advancing any 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

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in order to preserve our financial resources or to allow us adequate time to develop the required physical resources and systems and expertise ourselves.

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

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

Under the Genentech Agreement, the Merck Agreement and any other collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, and such disputes may be difficult and costly to resolve or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion, or to discontinue development of a particular product candidate. For example, in June 2017, Genentech gave notice that it is terminating the Genentech Agreement with respect to navoximod. Further, Genentech has the right to terminate the remainder of the Genentech Agreement for any reason, and Merck has the right to terminate the Merck Agreement for any reason, in each case, 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 AstraZeneca Agreement, Genentech Agreement and the Merck Agreement, and we may be required under other collaborations, to relinquish important rights to and control over the development of our product candidates to our collaborators or otherwise be subject to unfavorable terms.

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

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- other than under the AstraZeneca Agreement, Genentech Agreement and the Merck Agreement, we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;

we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;

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strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;

strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;

strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenues from these products;

disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;

strategic collaborators may experience financial difficulties;

strategic collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

business combinations or significant changes in a strategic collaborator's business strategy may also adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;

strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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

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

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

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

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

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.



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

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

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

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

In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products. Our failure to obtain a license to any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition and results of operations. Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any third party would be found to infringe our patents.

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

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



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

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

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

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

We 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:



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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 Genentech, Merck and AstraZeneca;

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.

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Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of September 30, 2017, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 56.2% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after September 30, 2017. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

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

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

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

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

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking only cash dividends should not purchase our common stock.

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

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management,

including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;

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the inability of stockholders to call special meetings; limitations on the ability of stockholders to remove directors or amend our by-laws; and the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors. In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

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

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

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

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

Based on Section 382 ownership change analyses, we believe that, from our inception through December 31, 2016, 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.

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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.



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### ITEM 1. LEGAL PROCEEDINGS

On or about May 12, 2016, Trevor Abramson filed a putative securities class action lawsuit in the United States District Court for the Southern District of New York, or the Court, captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Securities Action. Subsequently, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Securities Action. On October 31, 2016, the lead plaintiffs filed an amended complaint which asserts claims under the federal securities laws against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants. The amended complaint alleges the Defendants made material false and/or misleading statements that caused losses to the Company's investors. In particular, the lead plaintiffs allege that the Defendants made material misstatements or omissions related to the Phase II and III trials and efficacy of the product candidate algenpantucel-L. The lead plaintiffs do not quantify any alleged damages in the amended complaint but, in addition to attorneys' fees and costs, they seek 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. On April 27, 2017, the Court granted the parties' request for leave to brief a motion to dismiss the amended complaint, and ordered the parties to file a stipulation and proposed order setting forth a schedule for the briefing of that motion. On May 15, 2017, the Court ordered the following briefing schedule: motion to dismiss due July 14, 2017, opposition due September 12, 2017, and reply due September 26, 2017. The Defendants filed a motion to dismiss on July 14, 2017. The lead plaintiffs filed an opposition to the motion to dismiss on September 12, 2017. The Defendants filed a reply in support of the motion to dismiss on September 26, 2017. Oral argument was held on October 19, 2017, after which the Court reserved decision. The Company disputes the claims in the Securities Action and intends to defend against them vigorously.

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

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

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ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

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SIGNATURES

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

NEWLINK GENETICS  
CORPORATION

By: /s/ Charles J. Link, Jr.  
Charles J. Link, Jr.  
Chief Executive Officer  
(Principal Executive Officer)  
Date: November 3, 2017

By: /s/ John B. Henneman, III  
John B. Henneman, III  
Chief Financial Officer and  
Secretary  
(Principal Financial Officer)  
Date: November 3, 2017

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

Exhibit Number	Description	Incorporated By Reference			Filed Herewith
		Form	Filing Date	Number	
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Reference is made to Exhibits 3.1, 3.2 and 3.3 hereof				
4.3	Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
31.1	<u>Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)</u>				X
31.2	<u>Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)</u>				X
32.1	<u>#Section 1350 Certification</u>				X
101.INS	<u>‡XBRL Instance Document</u>				X
101.SCH	<u>‡XBRL Taxonomy Extension Schema Document</u>				X
101.CAL	<u>‡XBRL Taxonomy Extension Calculation Linkbase Document</u>				X
101.DEF	<u>‡XBRL Taxonomy Extension Definition Linkbase Document</u>				X
101.LAB	<u>‡XBRL Taxonomy Extension Label Linkbase Document</u>				X
101.PRE	<u>‡XBRL Taxonomy Extension Presentation Linkbase Document</u>				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.