NEWLINK GENETICS CORP
Form 10-Q
November 08, 2016
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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, 2016.
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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
(Do not check if a smaller reporting company)	

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

As of November 2, 2016, there were 29,134,623 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, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 148,276	$ 195,620
Certificates of deposit	—	2,180
Prepaid expenses and other current assets	10,688	4,954
Income tax receivable	5,197	—
Other receivables	14,995	5,388
Total current assets	179,156	208,142
Property and equipment, net	7,188	10,400
Total assets	$ 186,344	$ 218,542
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,367	$ 3,661
Accrued expenses	37,259	8,761
Income taxes payable	—	859
Current portion of unearned revenue	693	892
Current portion of deferred rent	81	96
Current portion of notes payable and obligations under capital leases	245	571
Total current liabilities	40,645	14,840
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	333	368
Unearned revenue	—	407
Deferred rent	1,089	1,153
Total long-term liabilities	7,422	7,928
Total liabilities	48,067	22,768
Stockholders' equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at September 30, 2016 and December 31, 2015; issued and outstanding shares — 0 at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at September 30, 2016 and December 31, 2015; issued 29,116,879 and 28,838,176 at September 30, 2016 and December 31, 2015, respectively, and outstanding 29,091,652 and 28,814,142 at September 30, 2016 and December 31, 2015, respectively	291	288
Additional paid-in capital	290,772	276,610
Treasury stock, at cost: 25,227 and 24,034 shares at September 30, 2016 and December 31, 2015, respectively	(784)	(771)
Accumulated deficit	(152,002)	(80,353)
Total stockholders' equity	138,277	195,774
Total liabilities and stockholders' equity	$ 186,344	$ 218,542

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,	
	2016	2015	2016	2015
Grant revenue	$14,457	$13,365	$20,057	$26,294
Licensing and collaboration revenue	888	844	3,008	34,555
Total operating revenues	15,345	14,209	23,065	60,849
Operating expenses:				
Research and development	24,463	22,508	73,810	56,619
General and administrative	7,749	7,384	26,043	23,007
Total operating expenses	32,212	29,892	99,853	79,626
Loss from operations	(16,867)	(15,683)	(76,788)	(18,777)
Other income and expense:				
Miscellaneous expense	(44)	—	(44)	—
Interest income	68	25	180	68
Interest expense	(5)	(88)	(18)	(98)
Other income (expense), net	19	(63)	118	(30)
Net loss before taxes	(16,848)	(15,746)	(76,670)	(18,807)
Income tax benefit (expense)	1,308	(160)	5,021	—
Net loss	$(15,540)	$(15,906)	$(71,649)	$(18,807)
Basic and diluted loss per share	$(0.54)	$(0.55)	$(2.48)	$(0.66)
Basic and diluted average shares outstanding	28,983,561	28,734,768	28,911,042	28,518,503

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, 2015	28,814,142	$ 288	$276,610	$ (771)	$ (80,353)	$ 195,774
Share-based compensation	—	—	13,119	—	—	13,119
Exercise of stock options and restricted stock vested	240,815	3	1,320	—	—	1,323
Sale of shares under stock purchase plan	37,888	—	363	—	—	363
Shares withheld for statutory tax withholding	(1,193)	—	—	(13)	—	(13)
Tax shortfall from employee stock plan awards	—	—	(640)	—	—	(640)
Net loss	—	—	—	—	(71,649)	(71,649)
Balance at September 30, 2016	29,091,652	$ 291	$290,772	$ (784)	$ (152,002)	$ 138,277

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2016	2015
Cash Flows From Operating Activities		
Net loss	$(71,649)	$(18,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	13,119	12,394
Depreciation and amortization	1,536	1,071
Forgiveness of debt	(397)	—
Impairment of fixed assets	3,976	—
Tax shortfall associated with employee stock plan awards	(640)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,734)	6,565
Other receivables	(9,607)	(11,261)
Accounts payable and accrued expenses	27,204	(1,780)
Income taxes receivable	(6,056)	8,687
Unearned revenue	(606)	(12,542)
Deferred rent	(79)	(62)
Net cash used in operating activities	(48,933)	(15,735)
Cash Flows From Investing Activities		
Maturity of certificates of deposit	2,180	9,177
Purchase of equipment	(2,069)	(3,450)
Net cash provided by investing activities	111	5,727
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	1,686	17,230
Repurchase of common stock	(13)	(341)
Payments under capital lease obligations and principal payments on notes payable	(195)	(144)
Net cash provided by financing activities	1,478	16,745
Net (decrease) increase in cash and cash equivalents	(47,344)	6,737
Cash and cash equivalents at beginning of period	195,620	190,404
Cash and cash equivalents at end of period	$148,276	$197,141
Supplemental disclosure of cash flows information:		
Cash paid for interest	$18	$37
Cash paid for taxes	$1,022	$4,808
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.

In 2005, NewLink created a partially owned subsidiary, BioProtection Systems Corporation (BPS). NewLink contributed certain licensing agreements and other intangible assets for BPS to create vaccines against potential biological terror threats. On January 7, 2011, NewLink acquired all of the minority interest in BPS by merging a newly formed subsidiary of NewLink with BPS, with BPS as the surviving corporation, resulting in NewLink owning all the outstanding capital stock of BPS.

In 2013, NewLink created a wholly-owned subsidiary, NewLink International (NI). NewLink plans to conduct all or a portion of its operations outside of the United States through NI. In 2014, NewLink created another wholly owned subsidiary, NewLink Global (NG), which was subsequently merged into NewLink during 2014.

NewLink and its subsidiaries (the Company) are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from commercial sales of its drugs. The Company incurred a net loss of $15.5 million and $71.6 million for the three and nine months ended September 30, 2016, respectively.

In May 2016, the Company announced that its Phase 3 clinical trial IMPRESS (IMmunotherapy for Pancreatic RESectable cancer Study) of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint and the Company's management adopted a restructuring plan designed to better align the Company's workforce and operating costs to its revised pipeline development plans and operating needs. The restructuring plan 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. In connection with the restructuring plan, the Company also discontinued the development of its commercial manufacturing capabilities for algenpantucel-L, discontinued programs supporting the future commercialization of algenpantucel-L, and recorded an impairment charge to fixed assets. The Company has retained some internal manufacturing ability to support the development of clinical supplies for its ongoing clinical trials of the other HyperAcute Cellular Immunotherapy product candidates. Refer to Note 9 for more information.

The accompanying condensed consolidated financial statements as of September 30, 2016 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 the at the market (ATM) offering. 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 offerings are expected to be adequate to satisfy the Company's liquidity requirements through 2018. 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, 2015, 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 2015. The financial results for any interim period are not necessarily indicative of financial results for the full year.

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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, certificates of deposit, receivables, and accounts payable are recorded at cost, which approximates fair value based on the short-term nature of these financial instruments. The carrying value of notes payable and capital lease obligations was $578,000 and $939,000 as of September 30, 2016 and December 31, 2015, respectively, which approximate fair value using Level 2 inputs. The Company is unable to estimate the fair value of the royalty obligation based on future product sales, as the timing of payments, if any, is uncertain.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. 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 $5.2 million and $6.5 million as of September 30, 2016 and December 31, 2015, 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 $14.0 million and $4.1 million of receivables from the government contracts recorded in other receivables and $9.7 million and $3.6 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, 2016 and December 31, 2015, respectively. The Company had $18.3 million and $1.1 million of accrued expenses for subcontractor fees incurred under the government contracts as of September 30, 2016 and December 31, 2015, respectively.

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Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2016-02, Leases, to improve financial reporting for leasing transactions. The new standard requires lessees to recognize on the balance sheet a right of use asset and related lease liability for all leases with terms greater than twelve months. The ASU also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. The effective date for public entities is fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for all entities. The Company is currently evaluating any impact this standard may have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No, 2016-09, Compensation—Stock Compensation: Improvements to Employee Share-Based Payment Accounting. The ASU includes multiple provisions intended to simplify various aspects of the accounting for share-based payments. While aimed at reducing the cost and complexity of the accounting for share-based payments, the amendments are expected to significantly impact net income, earnings per share, and the statement of cash flows. The effective date for public entities is for fiscal years beginning after December 15, 2016. Early adoption is permitted in any interim period provided that the entire ASU is adopted. The Company is currently evaluating any impact this standard may have on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The guidance will be effective for the fiscal year beginning after December 15, 2017, including interim periods within that year. The Company does not expect the adoption of this standard to have an impact on its condensed consolidated financial statements.

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 nine months ended September 30, 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 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 payments of over $1.0 billion upon achieving certain GDC-0919 and Next Generation Product Development regulatory development, international patent acceptance, country marketing approval, and sales-based milestones. The Company retains the right to exercise an option to co-promote GDC-0919 and any subsequent products for the U.S. market and is also eligible to receive escalating double digit royalty payments on potential commercial sales of multiple products by Genentech.

For the three and nine months ended September 30, 2016, the Company recognized license and collaboration revenue under the Genentech Agreement of $687,000 and $2.2 million, respectively, 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 (JRC). For the three and nine months ended September 30, 2015, the Company recognized license and collaboration revenue under the Genentech agreement of $808,000 and $14.4 million, respectively, including $2.0 million for amounts received as reimbursement for the Company's employees working on the project, $11.9 million for program materials

and technology transfer, $335,000 for providing an alliance manager, and $118,000 for participation in the JRC. In accordance with the Company's continuing performance obligation, $642,000 of the $150.0 million upfront payment remains deferred as of September 30, 2016 and will be recognized in future periods. The upfront payment provides no general right of return for any non-contingent deliverable and no portion of any revenue recognized is refundable.

Merck Sharp & Dohme Corp.

In November 2014, the Company entered into a licensing and collaboration agreement with Merck, or the Merck Agreement, to develop, manufacture and commercialize rVSV-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.

For the three and nine months ended September 30, 2016, the Company recognized license and collaboration revenues of $203,000 and $764,000, respectively, for the reimbursement of costs not covered under government contracts. For the nine months ended September 30, 2015, the Company recognized license and collaboration revenue under the Merck Agreement of $20.0 million associated with the one-time non-refundable milestone payment. For the three and nine months ended September 30, 2015, the Company recognized revenues of $36,000 and $170,000, respectively, associated with the remaining deliverables. In accordance with the Company's continuing performance obligations, $51,000 of the $30.0 million upfront payment remains deferred as of September 30, 2016 and will be recognized in future periods. The upfront payment provides no general right of return for any non-contingent deliverable, and no portion of any revenue recognized is refundable.

6. Common Stock Equity Incentive Plan

2009 Equity Incentive Plan

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

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

Awards under the 2009 Plan, as amended, may be made to officers, employees, members of the Board of Directors, advisors, and consultants to the Company. As of September 30, 2016, there were 9,071,674 shares of common stock authorized for the 2009 Plan and 910,275 shares remained available for issuance.

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(unaudited)

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

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 2016 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, 2016, zero 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, 2016, 193,504 shares remained available for issuance under the 2010 Purchase Plan.

Share-based Compensation

Share-based compensation expense for the three and nine months ended September 30, 2016 and 2015 was $3.9 million and $13.1 million, $3.3 million, and $12.4 million, respectively, and is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations. As of September 30, 2016, the total compensation cost related to nonvested option awards not yet recognized was $29.1 million and the weighted-average period over which it is expected to be recognized is 2.6 years.

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NewLink Genetics Corporation and Subsidiaries
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(unaudited)

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2016:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	5,646,480	$ 15.11	
Options granted	1,345,258	19.04	
Options exercised	(184,790)	7.15	
Options forfeited	(327,328)	31.97	
Options expired	(28,633)	21.47	
Outstanding at end of period	6,453,331	$ 15.27	6.0
Options exercisable at end of period	4,457,868	$ 11.11	4.7

The following table summarizes the range of assumptions used to estimate the fair value of stock options granted during the nine months ended September 30, 2016:

Risk-free interest rate	1.2%-2.0%
Expected dividend yield	—%
Expected volatility	67.1%-69.8%
Expected term (in years)	5.9-7.4
Weighted-average grant-date fair value per share	$11.91

The intrinsic value of options exercised during the nine months ended September 30, 2016 was $908,919. The fair value of awards vested during the nine months ended September 30, 2016 was $11.8 million.

Restricted Stock

Restricted stock is common stock that is subject to restrictions, including risks of forfeiture, determined by the plan committee of the Board of Directors in its sole discretion, for 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.

On January 4, 2016, the Company's Board of Directors approved grants of restricted stock unit awards to certain of the named executive officers for extraordinary performance in 2015. These are recognized as grants made in 2016. During the nine months ended September 30, 2016 and 2015, there were 115,566 and 131,610 shares of restricted stock granted, respectively, which vest over a four year period, with 25% vesting on each of the first, second, third and fourth anniversaries of the date the award was granted. The restricted stock grants as of September 30, 2016 and 2015 had a weighted average fair value per share of $34.73 and $43.66, respectively. Compensation expense is recognized for the issuance of restricted stock by amortizing over the requisite service period, or the vesting period, the aggregate fair value of the restricted stock awarded.

Additionally, during the three months ended March 31, 2016, the Company’s Board of Directors approved and granted 78,268 shares of performance restricted stock units. The performance restricted stock units had a weighted average fair value per share of $34.73. As a result of failure to meet certain criteria required for the vesting of the performance restricted stock units, 58,702 of the shares granted were forfeited during the second quarter of 2016. The remaining performance restricted stock units will vest upon the receipt of a milestone payment from Genentech under the Genentech Agreement upon the advancement of GDC-0919 into Phase 2 development. No compensation expense was

recognized for these performance restricted stock units during the nine months ended September 30, 2016.

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A summary of the Company's unvested restricted stock, including performance restricted stock, at September 30, 2016 and changes during the nine months ended September 30, 2016 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	228,972	$34.94
Granted	193,834	34.73
Vested	(56,025)	37.22
Forfeited/cancelled	(59,702)	34.58
Unvested restricted stock at end of period	307,079	$34.46

As of September 30, 2016, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $7.7 million and is expected to be recognized over a weighted-average period of 2.6 years. As of September 30, 2016, there remains approximately $680,000 of unrecognized compensation cost related to the issuance of performance restricted stock. The fair value of restricted stock, including performance restricted stock, granted during the nine months ended September 30, 2016 was $6.7 million. The fair value of awards vested during the nine months ended September 30, 2016 was $1.7 million.

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, 2016, the Company recorded an income tax benefit of $1.3 million and $5.0 million, respectively. For the three and nine months ended September 30, 2015, the Company recorded an income tax benefit of $160,000 and $0, respectively. The 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. federal income tax rate primarily due to the potential to carry back losses to 2014 and the net loss generated by NewLink's foreign subsidiary. Income tax expense for the three and nine months ended September 30, 2015 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes, the 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, 2016 and December 31, 2015, respectively, due to the uncertainty of future recoverability.

The Company has a reserve for uncertain tax positions related to state tax matters of $653,000 as of September 30, 2016 recorded within Accrued Expenses in the condensed consolidated balance sheet.

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.

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

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,	
	2016	2015	2016	2015
Loss attributable to common stockholders	$(15,540)	$(15,906)	$(71,649)	$(18,807)
Basic and diluted weighted-average shares outstanding	28,983,561	28,734,768	28,911,042	28,518,503
Basic and diluted loss per share	$(0.54)	$(0.55)	$(2.48)	$(0.66)

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. For the three and nine months ended September 30, 2016, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 6,453,331 and 307,079, respectively. For the three and nine months ended September 30, 2015, anti-dilutive stock options and restricted stock awards excluded from our calculation totaled 5,551,219 and 239,249, 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 order to 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 recorded an impairment charge for 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.

During the three months ended September 30, 2016, the Company did not record any additional restructuring charges. During the nine months ended September 30, 2016 the restructuring resulted in charges of $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. There were no restructuring charges recorded in prior periods.

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

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	Contract Termination Cost	Total
Balance as of December 31, 2015	—	$—	$—
Expensed	1,800,000	6,500,000	8,300,000
Cash Payments	1,528,000	85,000	1,613,000
Balance as of September 30, 2016	$272,000	$6,415,000	$6,687,000

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, against the Company, the Company’s Chief Executive Officer Charles J. Link, Jr., the Company’s Chief Financial Officer John B. Henneman III, and the Company’s former Chief Financial Officer Gordon H. Link, Jr., captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Action. On August 16, 2016, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Action. On August 26, 2016, the Court issued an order providing that (i) the lead plaintiffs shall file an amended complaint on or before October 31, 2016, (ii) the defendants shall submit a letter to the Court regarding a potential motion responsive to the amended complaint on November 15, 2016, and (iii) the lead plaintiffs shall submit a letter to the Court opposing the defendants’ letter on November 22, 2016. On October 31, 2016, the lead plaintiffs filed an amended complaint which asserts claims under the federal securities laws against the Company, Charles J. Link, Jr., and the Company’s Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants (no claims are asserted in the amended complaint against Messrs. Henneman or Gordon Link). 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. The Company disputes the claims in the Action and intends to defend against them vigorously.

11. Subsequent Events

The Company announced on October 4, 2016 that the Biomedical Advanced Research and Development Authority, or BARDA, of the United States Department of Health and Human Services issued a $24.8 million contract to a subsidiary of NewLink to support the advanced development of the investigational rVSVΔG-ZEBOV GP (Ebola Zaire) vaccine candidate, designated V920.

The new contract with BARDA includes an additional $51.2 million of contract options that may be exercised by BARDA. The funding provided by this contract will support manufacturing facility readiness, manufacturing process qualification activities and additional clinical trials to support regulatory approval of the V920 vaccine.

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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, 2015. 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 clinical stage immuno-oncology company focused on discovering and developing novel immunotherapeutic products for the treatment of cancer with an expertise in infectious diseases that drives specific opportunities. Our portfolio includes small-molecule and biologic immuno-oncology product candidates intended to treat a wide range of oncology indications. We have two small-molecule product candidates currently in clinical development that target key immune checkpoints: GDC-0919, in partnership with Genentech, Inc., a member of the Roche Group, or Genentech, and indoximod. These product candidates are IDO pathway inhibitors and focus on breaking the immune system's tolerance to cancer. Additionally, our biologic product candidates are based on our proprietary HyperAcute® Cellular Immunotherapy technology, which is designed to educate the human immune system. We have two HyperAcute Cellular Immunotherapy product candidates in clinical development, tergenpumatucel-L and dorgenmeltucel-L for patients with advanced lung cancer and melanoma, respectively. We believe that our immuno-oncology technologies have the potential to lead to multiple product candidates, targeting a wide range of oncology indications that could be used either alone or in combination with other therapies.

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The chart below summarizes our current IDO pathway inhibitor product candidates and their stages of development. We have an active drug discovery and clinical development program focused on the IDO (indoleamine-2, 3-dioxygenase) and TDO (tryptophan-2, 3-dioxygenase) pathways. Our small-molecule IDO pathway inhibitor product candidates currently in clinical development include GDC-0919 (in partnership with Genentech) and indoximod and are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. IDO pathway inhibitors are another class of immune checkpoint inhibitors akin to the recently developed antibodies targeting CTLA-4, PD-1 and PD-L1 that represent potential breakthrough approaches to cancer therapy. The IDO pathway regulates immune response by suppressing T-cell activation, which enables local tumor immune escape. The IDO pathway is active in many cancers, both within tumor cells as a direct defense against T-cell attack, and also within antigen presenting cells in tumor-draining lymph nodes, whereby this pathway promotes peripheral tolerance to tumor associated antigens, 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. Our IDO pathway inhibitors are representative of a key class of immune checkpoint inhibitors that we believe has the potential to be a breakthrough approach for patients with a variety of different cancer types. This type of molecule has the potential to be combined with different standard of care therapeutic approaches such as chemotherapy and radiotherapy or with novel cancer therapeutic approaches such as other immune checkpoint inhibitors, CAR T-cells or anti-tumor vaccines.

In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech for the development and commercialization of GDC-0919 and a research collaboration for the discovery of next-generation IDO and TDO pathway inhibitors, or the Genentech Agreement. Under the terms of the Genentech Agreement, we received an upfront non-refundable payment of $150.0 million. We may be eligible to receive in excess of $1.0 billion in milestone payments based on achievement of certain predetermined milestones as well as escalating double-digit royalties on potential commercial sales of multiple products by Genentech. Genentech will fund future research, development, manufacturing and commercialization costs. Genentech will also provide us with funding for support of the research collaboration through November 2016. We will continue to pursue development activities associated with GDC-0919 in combination with our novel HyperAcute Cellular Immunotherapy

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platform. We retain the option for co-promotion rights for GDC-0919 and potential next-generation IDO/TDO compounds in the United States.

GDC-0919 is currently in Phase 1 development led by our collaborators at Genentech. Two Phase 1 clinical trials are currently underway with GDC-0919. GDC-0919 is being evaluated in a Phase 1b combination clinical trial of GDC-0919 and atezolizumab (MPDL3280A) in patients with locally advanced or metastatic solid tumors. Enrollment began in July 2015 and a total enrollment of up to 276 patients is planned. A second Phase 1 clinical trial of GDC-0919 is ongoing evaluating dosing of GDC-0919 in patients with recurrent advanced solid tumors.

Indoximod, our proprietary IDO pathway inhibitor, is in multiple Phase 1 and Phase 2 clinical trials. These trials combine indoximod with both standard of care cancer immunotherapy treatments as well as standard of care chemotherapy for patients with cancer. Indoximod is currently being evaluated in clinical trials for patients with melanoma, pancreatic cancer, malignant brain tumors, metastatic breast cancer, acute myeloid leukemia, and non-small cell lung cancer.

Our HyperAcute Cellular Immunotherapy platform consists of novel biologic product candidates designed to educate the patient's immune system to recognize and attack cancer cells. HyperAcute Cellular Immunotherapy product candidates are composed of human cancer cell lines that are tumor specific, but not patient specific. These cells have been modified to express alpha-Gal, a carbohydrate for which humans have preexisting immunity. These alpha-Gal-modified cancer cells are designed to stimulate an immune response against cancer cells. The objective of HyperAcute Cellular Immunotherapy is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute Cellular Immunotherapies do not require any tissue from individual patients and use intact whole cells rather than cell fragments or purified proteins.

In May 2016, we announced that our Phase 3 clinical trial IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) for algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology failed to achieve its primary endpoint. In light of these results, we conducted an early analysis of our second Phase 3 clinical trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease). There was no difference in survival between the treatment group and the control group. This is preliminary data so the numbers may change slightly with data cleaning but the median survival was 14.6 months and 14.7 months for the treatment and control groups, respectively. The PILLAR study has been closed. Our additional HyperAcute Cellular Immunotherapy product candidates in clinical development include tergenpumatucel-L and dorgenmeltucel-L for patients with advanced lung cancer and melanoma, respectively.

We also have an active drug discovery program focused on Phosphatase and Tensin Homolog Deleted 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 potently immunosuppressive. It has been shown that 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 obtained in preclinical animal models, it is expected that the efficacy of PTEN inhibitors could 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 addition to our immuno-oncology programs, we have a team focused on developing vaccines against infectious diseases. Our infectious disease program researches and develops vaccines to control the spread of emerging lethal viruses and infectious diseases, improve the efficacy of existing vaccines and provide rapid-response prophylactic and therapeutic treatment for pathogens most likely to enter the human population through pandemics or acts of bioterrorism.

Our primary infectious disease program is a replication-competent recombinant vesicular stomatitis virus, or rVSV, an advanced vaccine technology developed for the Ebola and Marburg viruses. The rVSV-ZEBOV (Ebola) vaccine product candidate was originally developed by the Public Health Agency of Canada and is designed to utilize the rVSV vector to induce immunity against Ebola and Marburg viruses when replacing the VSV glycoprotein with corresponding glycoproteins from filoviruses. In November 2014, we entered into an exclusive, worldwide license and collaboration agreement, or the Merck Agreement, with Merck, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our rVSV-ZEBOV vaccine product candidate and certain other aspects of our vaccine technology. 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. In addition to milestone payments from Merck, the Company was awarded contracts for development of the rVSV-ZEBOV from the BioMedical Advanced Research & Development Agency and the Defense Threat Reduction Agency totaling $51.6 million during 2016 and $67.0 million during 2014 and 2015, for total awards of $118.6 million. In July 2015, we announced that the international partnership studying the rVSV-ZEBOV vaccine candidate in Guinea released interim data suggesting that it is effective in the prevention of Ebola disease in a large Phase 3 clinical trial. According to the announcement, the interim results suggest that the vaccine candidate

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demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-ZEBOV product candidate will continue to be studied in clinical trials.

In February 2016, we announced our initiative to develop a vaccine against the Zika virus. We believe that the experience gained in the development of our Ebola vaccine candidate will give us an advantage in this program.

We incurred a net loss of $71.6 million for the nine months ended September 30, 2016. 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.

Founded in 1999 and headquartered in Ames, Iowa, and Austin, Texas, we have a clinical, research and development staff dedicated to our pipeline of product candidates for patients with cancer and other diseases. Additionally, we have offices in Devens, Massachusetts, where we manage the development of and strategic relationships relating to our infectious disease program.

Restructuring Charges

In May 2016, we announced the IMmunotherapy for Pancreatic RESectable cancer Study (IMPRESS) Phase 3 study of algenpantucel-L for patients with resected pancreatic cancer did not achieve its primary endpoint. In May 2016, we adopted a restructuring plan designed to better align our workforce and operating costs to our revised pipeline development plans and operating needs.The restructuring plan included a reduction in our workforce; the exit of or reduction of certain leased facilities; and the renegotiation or termination of contracts with certain third parties. In connection with the restructuring plan, we also discontinued the development of our commercial manufacturing capabilities for algenpantucel-L, discontinued programs supporting the future commercialization of algenpantucel-L and recorded an impairment charge to fixed assets. We have retained some internal manufacturing ability to support the development of clinical supplies for our ongoing clinical trials of the other HyperAcute Cellular Immunotherapy 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, 2015, discusses our most critical accounting policies. Since December 31, 2015, there have been no material changes in the critical accounting policies discussed in our 2015 Annual Report.
Recent Accounting Pronouncements
See Note 3, Significant Accounting Policies, of the Notes to the Condensed Consolidated Financial Statements, for a discussion of the impact of new accounting standards on our condensed consolidated financial statements.

Results of Operations

Comparison of the Three Months Ended September 30, 2016 and 2015

Revenues. Revenues for the three months ended September 30, 2016 were $15.3 million, an increase of $1.1 million from $14.2 million for the same period in 2015. The increase in revenue of was primarily due to an increase in grant revenue of $1.1 million.

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2016 were $24.5 million, an increase of $2.0 million from $22.5 million for the same period in 2015. The increase was primarily due to a $3.2 million increase in contract manufacturing costs, a $340,000 increase in stock compensation expense, and a $400,000 increase in clinical trial expenses, offset by a decrease in equipment and supplies of $1.3 million, a decrease in wages of $480,000 and a $160,000 decrease in consulting expenses.

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General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2016 were $7.7 million, an increase of $365,000 from $7.4 million for the same period in 2015. The increase was due primarily to an increase of $300,000 in consulting and personnel-related expenses.

Income Tax Benefit. The income tax benefit for the three months ended September 30, 2016 was $1.3 million, compared to income tax expense of $160,000 for the same period in 2015. The change of $1.5 million is primarily due to the change in the effective tax rate. 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 2016 back to prior years.

Net Loss. The net loss for the three months ended September 30, 2016 was $15.5 million compared to net loss of $15.9 million for the same period in 2015. The $366,000 decrease in the net loss was due primarily to an increase in operating expenses of $2.3 million offset by the increase in revenues of $1.1 million and the change in the income tax benefit of $1.5 million as discussed above. The basic and diluted weighted average common shares outstanding for the three months ended September 30, 2016 were 28,983,561, resulting in a basic and diluted loss per share of $0.54. For the three months ended September 30, 2015, the basic and diluted weighted average common shares outstanding were 28,734,768, resulting in basic and diluted loss per share of $0.55.

Comparison of the Nine Months Ended September 30, 2016 and 2015

Revenues. Revenues for the nine months ended September 30, 2016 were $23.1 million, a decrease of $37.7 million from $60.8 million for the same period in 2015. The decrease in revenues was due to a decrease of $6.2 million in grant revenue and a decrease of $31.5 million in licensing and collaboration revenue. Licensing and collaboration revenue was higher for the nine months ended September 30, 2015 due to the recognition of a one-time $20.0 million non-refundable milestone payment in February 2015 from Merck and the recognition of revenue under the Genentech Agreement of $9.5 million associated with license and manufacturing technology transfer deliverables and $2.7 million associated with delivery of supplies and other items, all of which were completed in their entirety during the nine months ended September 30, 2015.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2016 were $73.8 million, an increase of $17.2 million from $56.6 million for the same period in 2015. The increase was due to $11.8 million of charges incurred as a result of the restructuring during the second quarter of 2016, including a non-cash charge of $4.0 million related to impaired assets, a $3.1 million increase in contract manufacturing costs, a $4.4 million increase in supplies and equipment and a $1.3 million increase in wages, offset by a decrease in clinical trial expense of $2.4 million and a decrease in stock compensation expense of $1.0 million.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2016 were $26.0 million, an increase of $3.0 million from $23.0 million for the same period in 2015. The increase was due to an increase of $3.3 million in personnel-related expenses due to changes in transiently increased staffing levels, share-based compensation expense and compensation increases, $500,000 due to charges incurred as a result of the restructuring, offset by a decrease of $800,000 in consulting, legal and licensing fees, and supplies.

Income Tax Benefit. The income tax benefit for the nine months ended September 30, 2016 was $5.0 million, compared to income tax benefit of $0 for the same period in 2015. The change of $5.0 million is primarily due to the change in the effective tax rate. 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 2016 back to prior years.

Net Loss. The net loss for the nine months ended September 30, 2016 was $71.6 million compared to net loss of $18.8 million for the same period in 2015. The $52.8 million increase in the net loss was due to the decrease in revenues of $37.7 million accompanied by an increase in operating expenses of $20.2 million offset by the change in the income tax benefit of $5.0 million as discussed above. The basic and diluted weighted average common shares outstanding for the nine months ended September 30, 2016 were 28,911,042 resulting in a basic and diluted loss per share of $2.48. For the nine months ended September 30, 2015, the basic and diluted weighted average common shares outstanding were 28,518,503, resulting in basic and diluted loss per share of $0.66.

Liquidity and Capital Resources

As of September 30, 2016, we had cash and cash equivalents of $148.3 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. 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.

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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;
- 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.

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,	
	2016	2015
Net cash used in operating activities	$(48,933)	$(15,735)
Net cash provided by investing activities	111	5,727
Net cash provided by financing activities	1,478	16,745
Net (decrease) increase in cash and cash equivalents	$(47,344)	$6,737

For the nine months ended September 30, 2016 and 2015, we used cash of $48.9 million and $15.7 million, respectively, for our operating activities. For the nine months ended September 30, 2016, the sources and uses of cash in this period primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities. The net loss for this period was primarily due to increased operating expenses in excess of licensing and grant revenue and expenses of $12.3 million incurred as a result of the restructuring plan committed to by the Company's management team in May 2016.

For the nine months ended September 30, 2016 and 2015, our investing activities provided cash of $111,000 and $5.7 million, respectively. The cash provided by investing activities in 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. The cash provided by investing activities in the nine months ended September 30, 2015 was due to maturity of certificates of deposit for $9.2 million offset by $3.5 million in purchases of property and equipment.

For the nine months ended September 30, 2016 and 2015, our financing activities used cash of $1.5 million and provided cash of $16.7 million, respectively. The cash provided by financing activities in the nine months ended September 30, 2016 was due to the 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 repurchases of common stock of $13,000. The cash provided by financing activities in the nine months

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ended September 30, 2015 was primarily due to the sale and issuance of common stock for net proceeds of $17.2 million, offset by the repurchase of common stock of $341,000 and net payments on long-term obligations and notes payable of $144,000.

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, 2015.

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, 2016 and December 31, 2015, we had cash and cash equivalents and certificates of deposit of $148.3 million and $197.8 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, 2016. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of September 30, 2016, 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.

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

We have an ongoing research program to investigate potential opportunities to improve the potency, efficacy and/or safety profile of some of our product candidates through modifications to their formulations or chemical compositions. These efforts may not be successful. If a new formulation or composition appears promising, we may decide to undertake clinical development of such formulation or composition even if an existing product candidate has shown acceptable safety and efficacy in clinical trials. The nature and extent of additional clinical trials that might be required for a new formulation or composition would depend on many factors. If we were to decide to pursue clinical development of a new formulation or composition, we would incur additional costs and the timeline for potential commercialization would be delayed. There can be no assurance that any new formulation or composition would prove to be safe or effective or superior to an existing product candidate. Any delay in commercialization of a new formulation or composition may adversely affect our competitive position.

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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 competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- we may experience delays in achieving clinical trial endpoints and completing data analysis for a trial.

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

own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol or applicable regulations. We also may rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner.

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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;
- 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.

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.

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Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

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

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

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

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

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

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

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

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

fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;

- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or
- insufficient quantities of the product candidate to complete the trials.

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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, our HyperAcute Cellular Immunotherapy product candidates, 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 proprietary 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 is being studied in clinical trials in West Africa. We may continue to supply and otherwise support similar trials in the future. However, because we are not the sponsors of these trials, we do not control the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment, and, as a result, are subject to risks associated with the way these types of trials are conducted, in particular should any problems arise. These risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data.

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

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

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

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

Even if approved, indoximod, GDC-0919, the HyperAcute Cellular Immunotherapy product candidates, 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 no experience in preparing

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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 arrangements for third-party contract manufacturing for some or all of 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 Genentech Agreement in October 2014 for the sales, marketing and distribution of GDC-0919, and we entered into the Merck Agreement in November 2014 for the research, development, manufacture and distribution of our Ebola vaccine product candidate. Even if GDC-0919 or our Ebola vaccine product candidate are approved by regulators for marketing and sale, Genentech or Merck may be unsuccessful in their efforts to commercialize GDC-0919 or our Ebola vaccine product candidate, respectively, or may devote fewer resources to such efforts than we would consider optimal.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products, including to co-promote GDC-0919, 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
- 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, particularly Dr. Charles J. Link, Jr. and Dr. Nicholas N. Vahanian. The loss of services by either of these leaders 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.

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We will need to recruit a significant number of additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. 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 approved product candidates. 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 other product candidates or market them.

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 previously 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 drugs, 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.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products. All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including our Company, our existing contract manufacturers and those we may engage in the future, and Genentech and Merck in their respective capacities as our licensees, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale

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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.

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.

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

We intend to rely in whole or in part on contract manufacturers or strategic partners for the manufacture of all of our product candidates for commercial sale, if any are approved for sale. In addition, we currently rely on contract manufacturers for the supply of our Ebola vaccine product candidate and indoximod 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, our Ebola vaccine product candidate, components of the HyperAcute Cellular Immunotherapy product candidates or other finished products. This could delay or reduce commercial sales and materially harm our business. 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. 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. Further, if our current or future contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

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

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

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

We have experienced bacterial and mycoplasma contaminations in lots produced at our facilities, and we destroyed the contaminated lots and certain overlapping lots. We may experience additional contaminations at our facilities, and we will destroy any contaminated lots that we detect, which could result in significant delay in our ability to produce material for clinical trials.

We rely on a single manufacturer for a key component used in the manufacture of our HyperAcute Cellular Immunotherapy product candidates, which could impair our ability to manufacture and supply our products.

The manufacturing process for our HyperAcute Cellular Immunotherapy product candidates has one component that we obtain from a single manufacturer. If our current supplier is unable to continue supplying the component for our clinical trials, we may need to utilize an alternative manufacturer. If we utilize an alternative manufacturer, we may be required to demonstrate comparability of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

Our 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 facilities are therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business 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

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

Risks Relating to Regulation of Our Industry

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

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

There can be no assurance that 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. To date, the FDA has approved only one active cellular cancer immunotherapy product, even though several have been, and currently are, in clinical development.

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,

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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 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 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 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 reimbursement to the consumer from third-party payers, such as government and private insurance plans. 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 recent years. 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

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programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly. 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. Recently, several pharmaceutical and other health-care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of off-label promotion. 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; and 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, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, 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.

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

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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. 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 United States, the pharmaceutical industry has already been significantly affected by major legislative initiatives, including, for example, the Affordable Care Act, or ACA. The ACA, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, and impose additional health policy reforms, any or all of which may affect our business. The ACA, compounded by the intense public scrutiny of drug pricing in the United States, is likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Other legislative changes have also been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions in Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Such laws, and others that may affect our business that have been recently enacted or may in the future be enacted, may result in additional reductions in Medicare and other healthcare funding. In the future, there will likely continue to be additional 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.

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

Some of our product candidates may be regulated as biological products, or biologics, which may subject them to competition sooner than anticipated.

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With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the ACA, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. To be considered biosimilar, a product candidate must be highly similar to the reference product notwithstanding minor differences in clinically inactive components. In addition, there can be no clinically meaningful differences between the product candidate and the reference product in terms of the safety, purity and potency of the product. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The BPCIA is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological product candidates.

Under the BPCIA, no approval of an application for a biosimilar product may be made effective until 12 years after the original branded product is first licensed by the FDA pursuant to the approval of a BLA. If any of our biological product candidates are approved by the FDA and qualify for this 12-year period of market exclusivity, known as reference product exclusivity, no approval of a biosimilar version of our product could become effective prior to the expiration of that 12-year period. However, these exclusivity provisions have been subject to various interpretations that have not yet been fully addressed by the FDA and there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our biological product candidates to be eligible for reference product exclusivity, potentially creating the opportunity for competition sooner than anticipated. In addition, even one of our biological product candidates were to receive reference product exclusivity, a competitor may seek approval of a product candidate under a full BLA rather than a biosimilar product application. In such a case, although the competitor would not enjoy the benefits of the abbreviated pathway for biosimilar approval created under the BPCIA, the FDA would not be precluded from making effective an approval of the competitor product pursuant to a BLA prior to the expiration of our 12-year period of marketing exclusivity.

In addition, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear. In particular, it is unclear at this juncture whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies. Such substitution will depend on a number of marketplace and regulatory factors that are still developing.

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 in 2015 and the third quarter of 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 GDC-0919 or other licensed products. The potential milestone and royalty payments under the Genentech Agreement are highly uncertain and dependent on many factors outside of our control related to possible future clinical trials and commercialization. We do not expect any milestone or royalty payments

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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 $15.5 million in the third quarter of 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 our operating losses will substantially increase over the next several years as we expand both our commercialization activities and our discovery and research activities.

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

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

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

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, 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 and certificates of deposit will allow us to fund our operating plan through 2018. However, our operating plan may change as a result of factors currently unknown to us. There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of

our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from approximately $200,000 to $2.8 million per license (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding

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milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

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

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

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

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

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

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

We anticipate that we will have a tax benefit for the year ended December 31, 2016 due to our ability to carry net operating losses back to the year ended December 31, 2014 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,

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more effective or less costly than any that we may develop. Such companies also may be more successful than we are in production and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection and establish collaborative arrangements for the development of oncology products.

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

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

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

We face intense competition in our development activities. We face competition from many companies in the United States and abroad, including a number of large pharmaceutical companies, firms specialized in the development and production of vaccines, checkpoint inhibitors, and other immunotherapies, and major universities and research institutions. Our competitors in the field of immuno-oncology and cancer vaccines include AdaptImmune LLC, Aduro Biotech, Advaxis, Inc., AstraZeneca PLC, Bristol Myers-Squibb Company, Celgene Corporation, GlaxoSmithKline plc, Idera Pharmaceuticals, Inc., Immune Design Corp., Incyte Corporation, Merck & Co., Inc., Merrimack Pharmaceuticals, Inc., Novartis AG, Pfizer Inc., Roche Holding Ltd, and Sanofi SA, among others. Many other companies are developing or commercializing products in areas that we have targeted for product development. Some of these products use therapeutic approaches that may compete directly with our 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. 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.

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Research and discoveries by others may result in breakthroughs that render indoximod, GDC-0919, 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. In particular, given the widespread media attention on the recent Ebola epidemic and outbreak of the Zika virus, there are competitive efforts by public and private entities to develop vaccines for these viruses as fast as possible. There are at least 14 companies who have publicly announced that they are developing a Zika vaccine and two of these, Inovio Pharmaceuticals, Inc. and Bharat Biotech Ltd. have developed Zika vaccine product candidates that are in clinical trials. These other entities may develop Ebola or Zika vaccines that are more effective than any we or our collaborators may develop, or may develop an Ebola or Zika vaccine at a lower cost or earlier than we or our collaborators are able to develop, or they may be more successful at commercializing an Ebola or Zika vaccine. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our Ebola or Zika vaccine development efforts. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to infectious disease or biodefense products.

Our future products, if any, may not be accepted in the marketplace 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 partners and the third parties that they may use, to conduct our preclinical studies and clinical trials. Other than to the extent that Genentech and Merck are responsible for clinical trials of GDC-0919 and our Ebola vaccine product candidate, respectively, we are responsible for confirming that our 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.

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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, respectively. If either company does not succeed in advancing any product candidate to final approval, such failure could materially harm our business.

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

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

If we enter into a collaboration agreement we consider acceptable, including the Genentech Agreement to commercialize GDC-0919 and the Merck Agreement to commercialize our Ebola vaccine product candidate, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

- the collaborator may not apply the expected 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 future collaboration for our product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates, disputes that may be difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the potential product may have the right to terminate the collaboration at its discretion. For example, Genentech has the right to terminate the Genentech Agreement for any reason after October 16, 2016, and Merck has the right to terminate the Merck Agreement for any reason after a specified advance notice period. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or may require us to delay or scale back the commercialization efforts. The occurrence of any of these events could adversely affect the commercialization of the potential product and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA, by slowing the growth of such sales, by reducing the profitability of the product and/or by

adversely affecting the reputation of the product.

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

We may, in the future, periodically explore a variety of possible strategic collaborations in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in 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

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collaborations because of the numerous risks and uncertainties associated with establishing them.

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

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

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

Risks Relating to Protecting Our Intellectual Property

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

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

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

were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we have not filed for patent protection or where patent protection may be unavailable, not obtainable or ultimately not enforceable. In addition,

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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.

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

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

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

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

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

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

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

results of operations.

We also rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not issued. We attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our

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consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

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

Risks Relating to Our Exposure to Litigation

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

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

We currently carry clinical trial liability insurance in the amount of $5.0 million in the aggregate for claims related to our drug candidates other than our Ebola vaccine product candidate. We currently carry clinical trial liability insurance in the amount of $10.0 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.

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Risks Related to Ownership of Our Common Stock

The market price of our common stock may be highly volatile, and could decline significantly.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including those described elsewhere in this "Risk Factors" section of this Quarterly Report on Form 10-Q and the following:

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including those relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- expenses related to, or our ability or perceived ability to secure, an adequate supply of any future products approved for commercial sale;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures and capital commitments;
- the commercial or clinical success or failure, or perceived success or failure, of our collaborators, including Genentech and Merck;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- media attention, or changes in media attention, 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, 2016 our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 52.7% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after September 30, 2016. 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, our ability to pay cash dividends is currently prohibited by the terms of one of our debt financing arrangements, and any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking 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, 2015, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage

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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, against the Company, the Company's Chief Executive Officer Charles J. Link, Jr., the Company's Chief Financial Officer John B. Henneman III, and the Company's former Chief Financial Officer Gordon H. Link, Jr., captioned Abramson v. NewLink Genetics Corp., et al., Case 1:16-cv-3545, or the Action. On August 16, 2016, the Court appointed Michael and Kelly Nguyen as lead plaintiffs and approved their selection of Kahn, Swick & Foti, LLC as lead counsel in the Action. On August 26, 2016, the Court issued an order providing that (i) the lead plaintiffs shall file an amended complaint on or before October 31, 2016, (ii) the defendants shall submit a letter to the Court regarding a potential motion responsive to the amended complaint on November 15, 2016, and (iii) the lead plaintiffs shall submit a letter to the Court opposing the defendants' letter on November 22, 2016. On October 31, 2016, the lead plaintiffs filed an amended complaint which asserts claims under the federal securities laws against the Company, Charles J. Link, Jr., and the Company's Chief Medical Officer and President Nicholas Vahanian, or collectively, the Defendants (no claims are asserted in the amended complaint against Messrs. Henneman or Gordon Link). 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. The Company disputes the claims in the Action and intends to defend against them vigorously.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The 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 8, 2016

By: /s/ John B. Henneman, III
John B. Henneman, III
Chief Financial Officer and
Secretary
(Principal Financial Officer)
Date: November 8, 2016

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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.

		Incorporated By Reference			
Exhibit Number	Description	Form	Filing Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2	Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3	Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1	Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2	Reference is made to Exhibits 3.1, 3.2 and 3.3 hereof				
4.3	Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1	†2010 Non-Employee Directors' Stock Award Plan, as amended.				X
31.1	Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2	Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1	#Section 1350 Certification				X
101.INS	‡XBRL Instance Document				X
101.SCH	‡XBRL Taxonomy Extension Schema Document				X
101.CAL	‡XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	‡XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	‡XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	‡XBRL Taxonomy Extension Presentation Linkbase Document				X

†Indicates management contract or compensatory plan.

#The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NewLink Genetics Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

‡Filed herewith electronically.