NEWLINK GENETICS CORP
Form 10-Q
November 06, 2015
Table of Contents

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, 2015.
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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of November 3, 2015, there were 28,785,448 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

Table of Contents

NewLink Genetics Corporation
FORM 10-Q
Table of Contents

Table of Contents

PART I

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

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$197,141	$190,404
Certificates of deposit	3,216	12,393
Prepaid expenses	1,768	8,333
Income tax receivable	76	8,763
State research and development credit receivable	472	13
Other receivables	14,518	3,716
Total current assets	217,191	223,622
Leasehold improvements and equipment:		
Leasehold improvements	7,086	6,022
Computer equipment	2,325	1,399
Lab equipment	5,168	4,110
Contract manufacturing organization equipment	1,075	1,023
Total leasehold improvements and equipment	15,654	12,554
Less accumulated depreciation and amortization	(6,026)	(4,955)
Leasehold improvements and equipment, net	9,628	7,599
Total assets	$226,819	$231,221

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	September 30, 2015	December 31, 2014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,494	$2,412
Accrued expenses	8,155	9,367
Current portion of unearned revenue	901	12,966
Current portion of deferred rent	85	84
Current portion of obligations under capital leases	22	35
Current portion of notes payable	558	157
Total current liabilities	11,215	25,021
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	409	941
Unearned revenue	608	1,085
Deferred rent	1,175	1,238
Total long-term liabilities	8,192	9,264
Total liabilities	19,407	34,285
Stockholders' Equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at September 30, 2015 and December 31, 2014; issued and outstanding shares — 0 at September 30, 2015 and December 31, 2014	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at September 30, 2015 and December 31, 2014; issued 28,792,711 and 27,991,242 at September 30, 2015 and December 31, 2014, respectively, and outstanding 28,774,911 and 27,980,849 at September 30, 2015 and December 31, 2014, respectively	288	280
Additional paid-in capital	266,454	236,838
Treasury stock, at cost: 17,800 and 10,393 shares at September 30, 2015 and December 31, 2014, respectively	(551)	(222)
Accumulated deficit	(58,779)	(39,960)
Total stockholders' equity	207,412	196,936
Total liabilities and stockholders' equity	$226,819	$231,221

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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,	
	2015	2014	2015	2014
Grant revenue	$13,365	$2,801	$26,294	$3,347
Licensing and collaboration revenue	844	—	34,555	—
Total operating revenues	14,209	2,801	60,849	3,347
Operating expenses:				
Research and development	22,508	10,896	56,619	23,760
General and administrative	7,384	4,931	23,007	11,044
Total operating expenses	29,892	15,827	79,626	34,804
Loss from operations	(15,683)	(13,026)	(18,777)	(31,457)
Other income and expense:				
Interest income	25	20	68	65
Interest expense	(88)	(5)	(98)	(18)
Other (expense) income, net	(63)	15	(30)	47
Loss before taxes	(15,746)	(13,011)	(18,807)	(31,410)
Income tax (expense) benefit	(160)	7,413	—	7,413
Net loss	$(15,906)	$(5,598)	$(18,807)	$(23,997)
Basic and diluted loss per share	$(0.55)	$(0.20)	$(0.66)	$(0.86)
Basic and diluted average shares outstanding	28,734,768	27,914,782	28,518,503	27,800,246

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	27,980,849	$280	$236,838	$(222)	$ (39,960)	$ 196,936
Share-based compensation	—	—	12,394	—	—	12,394
Exercise of stock options and restricted stock vested	453,079	5	3,290	—	—	3,295
Sale of shares under stock purchase plan	18,988	—	401	—	—	401
Issuance of common stock under the ATM Offering (net of offering costs of $692)	329,402	3	13,531	—	—	13,534
Shares withheld for statutory tax withholding	(7,949)	—	—	(341)	—	(341)
Issuance of common stock from treasury	542	—	—	12	(12)	—
Net loss	—	—	—	—	(18,807)	(18,807)
Balance at September 30, 2015	28,774,911	$288	$266,454	$(551)	$ (58,779)	$ 207,412

See accompanying notes to condensed consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2015	2014
Cash Flows From Operating Activities		
Net loss	$(18,807)	$(23,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	12,394	6,901
Depreciation and amortization	1,071	814
Changes in operating assets and liabilities:		
Prepaid expenses	6,565	420
State research and development credit receivable	(459)	(150)
Other receivables	(10,802)	(1,392)
Accounts payable and accrued expenses	(1,780)	3,489
Income taxes receivable	8,687	(7,632)
Unearned revenue	(12,542)	—
Deferred rent	(62)	(62)
Net cash used in operating activities	(15,735)	(21,609)
Cash Flows From Investing Activities		
Purchase of certificates of deposit	—	(16,387)
Maturity of certificates of deposit	9,177	—
Purchase of equipment	(3,450)	(1,344)
Net cash provided by (used in) investing activities	5,727	(17,731)
Cash Flows From Financing Activities		
Issuance of common stock, net of offering costs	17,230	29,382
Repurchase of common stock	(341)	(222)
Proceeds from notes payable	—	97
Principal payments on notes payable	(117)	(115)
Payments under capital lease obligations	(27)	(23)
Net cash provided by financing activities	16,745	29,119
Net increase (decrease) in cash and cash equivalents	6,737	(10,221)
Cash and cash equivalents at beginning of period	190,404	61,291
Cash and cash equivalents at end of period	$197,141	$51,070
Supplemental disclosure of cash flows information:		
Cash paid for interest	$37	$18
Cash paid for taxes	4,808	143
Cash received from income tax refund	13,500	—
Noncash financing and investing activities:		
Purchased leasehold improvements and equipment in accounts payable	350	—

See accompanying notes to condensed consolidated financial statements.

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

1. Description of Business

On June 4, 1999, NewLink Genetics Corporation (NewLink) was incorporated as a Delaware corporation. NewLink was formed for the purpose of developing treatments for cancer and other diseases. NewLink initiated operations in April 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 had a net loss of $15.9 million and $18.8 million for the three and nine months ending September 30, 2015, respectively.

The accompanying financial statements as of September 30, 2015 and for the three and nine months then ended have been prepared assuming the Company will continue as a going concern. The Company successfully raised net proceeds of $37.6 million from its 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 ATM Offering prior to March 31, 2015. 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 an additional 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 2016, although not through commercialization and launch of revenue-producing products. If available liquidity becomes insufficient to meet the Company’s operating obligations as they come due, the Company's plans include pursuing alternative funding arrangements and/or reducing expenditures as necessary to meet the Company’s cash requirements. However, there is no assurance that, if required, the Company will be able to raise additional capital or reduce discretionary spending to provide the required liquidity. Failure by the Company to successfully execute its plans or otherwise address its liquidity needs may have a material adverse effect on its business and financial position, and may materially affect the Company’s ability to continue as a going concern.

2. Basis of Presentation

The interim financial statements have been prepared and presented by the Company in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (the SEC), without audit, 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, 2014, 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 2014. The financial results for any interim period are not necessarily indicative of financial results for the full year.

3. Significant Accounting Policies

(a) Use of Estimates

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

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

(b) 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.
(c) 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 fair value and carrying value of notes payable and capital lease obligations was $989,000 and $1.1 million as of September 30, 2015 and December 31, 2014, respectively, and was determined 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 and certificates of deposit. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company’s cash and cash equivalents balance exceeds the federally insured limits. To limit the credit risk, the Company invests its excess cash primarily in high-quality securities such as certificates of deposit.
(d) Immaterial Error Correction
Included in the balance sheet as of December 31, 2014 is an immaterial error correction related to the provision for income taxes. The income tax receivable as of December 31, 2014 has been decreased by $6.8 million. Due to this error, the Company’s net income and stockholders’ equity were both correspondingly overstated for the year ending December 31, 2014 by $6.8 million. There was no impact to the net cash provided by operating activities in the consolidated statement of cash flows for the year ending December 31, 2014.

The immaterial error correction also resulted in an increase in the Company's deferred tax asset and a corresponding increase to the valuation allowance as there is a full valuation allowance against net deferred tax assets due to the uncertainty of future recoverability.
(e) Recent Accounting Pronouncements
On May 28, 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on January 1, 2018; however, early adoption at January 1, 2017, is permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet selected a transition method, nor has it determined the effect of the standard on its ongoing financial reporting.

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

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 provides the Company with financial assistance to construct new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until March 31, 2016.

The project calls for the Company to create or retain at least 150 full-time positions located in Ames, Iowa. In March 2015, the City of Ames granted a one-year extension for the deadline to obtain the required number of jobs to 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. If, as of March 10, 2016, the Company has fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2016, the Company has failed to create or retain at least 150 full-time jobs in Ames, Iowa, the Company will be required to repay approximately $3,100 per job not created or retained following such date. As of September 30, 2015, $397,000 of the total $400,000 forgivable loan was advanced to the Company. As of September 30, 2015, the Company has created or retained at least 150 full-time positions in Ames, Iowa. In the event of default, including failure to repay any amounts under the loan when due, the Company will be required to repay the note, including 6.5% interest per annum, beginning at the date of default.

5. 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 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, 2015 the Company recognized license and collaboration revenue under the Genentech Agreement of $808,000 and $14.4 million, respectively, associated with license and manufacturing technology transfer deliverables, which were completed in their entirety during the period and reimbursement for certain wages. In accordance with the Company’s continuing performance obligation, $1.5 million of the $150.0 million upfront payment is being deferred and 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.

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

For the nine months ended September 30, 2015 the Company recognized 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 license and collaboration revenues of $36,000 and $170,000, respectively, associated with the remaining deliverables. In accordance with the Company's continuing performance obligations, $63,000 of the $30.0 million upfront payment is being deferred and 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, 2015, there were 7,192,547 shares of common stock authorized for the 2009 Plan and 858,696 shares remained available for issuance.

On May 15, 2010 and January 7, 2011, stockholders authorized increases of 1,238,095 and 714,286 shares of common stock available for issuance under the 2009 Plan, respectively. On January 1, 2013, 2014, and 2015, an additional 838,375, 1,066,340 and 1,119,255 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan, respectively, 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, 2015, 131,632 shares remained available for issuance under the 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, 2015, 252,652 shares remained available for issuance under the plan.

Share-based Compensation

Share-based compensation expense for the three and nine months ended September 30, 2015 was $3.3 million, and $12.4 million, respectively, and for the three and nine months ended September 30, 2014 was $3.3 million, and $6.9 million, respectively, and is allocated between research and development and general and administrative expenses within the condensed consolidated statements of operations, giving rise to related tax benefits of $0 for all periods. During the nine months ended September 30, 2015, there was $2.4 million in share-based compensation expense that

was classified as research and development expense resulting from the vesting in full of an employee's options upon the employee's departure from the Company.

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

As of September 30, 2015, the total compensation cost related to nonvested option awards not yet recognized was $30.2 million and the weighted-average period over which it is expected to be recognized is 3.0 years.

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2015:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	5,132,451	$9.46	
Options granted	878,945	43.44	
Options exercised	(414,471)	7.94	
Options forfeited	(45,706)	37.20	
Options expired	—	—	
Outstanding at end of period	5,551,219	$14.72	6.2
Options exercisable at end of period	3,829,065	$7.23	5.0

The following table summarizes the range of assumptions used to estimate the fair value of stock options issued during the nine months ended September 30, 2015:

Risk-free interest rate	1.5%-2.0%
Expected dividend yield	—%
Expected volatility	62.5%-65.6%
Expected term (in years)	5.9-7.0
Weighted-average grant-date fair value per share	$26.81

The intrinsic value of options exercised during the nine months ended September 30, 2015 was $16.5 million. The fair value of awards vested during the nine months ended September 30, 2015 was $6.6 million. The fair value of options vested for the nine months ended September 30, 2015 includes the fair value of options with accelerated vesting as a result of an employee's departure from the Company of $2.8 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 2, 2015, the Company's Board of Directors approved grants of restricted stock unit awards to certain of the named executive officers for extraordinary performance in 2014. These are recognized as grants made in 2015. During the nine months ended September 30, 2015 and 2014, there were 131,610 and 138,420 shares of restricted stock granted, respectively. These restricted stock grants as of September 30, 2015 and 2014 had a weighted average fair value (per share) at date of grant of $43.66 and $21.82, respectively. At September 30, 2015 and 2014, there were 239,249 and 92,720 shares of unvested restricted stock outstanding, 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 based on the closing price of the Company's common stock on the date of grant.

12

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

A summary of the Company's unvested restricted stock at September 30, 2015 and changes during the nine months ended September 30, 2015 are as follows:

	Number of restricted stock shares	Weighted average grant date fair value
Unvested at beginning of period	153,509	$23.63
Granted	131,610	43.66
Vested	(38,070)	21.62
Forfeited/cancelled	(7,800)	43.65
Unvested restricted stock at end of period	239,249	$34.32

As of September 30, 2015, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $6.6 million and is expected to be recognized over a weighted-average period of 3.0 years. The grant date fair value of awards granted during the nine months ended September 30, 2015 was $5.8 million. The fair value of awards vested during the nine months ended September 30, 2015 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, 2015, the Company recorded income tax expense of $160,000 and $0, respectively. For the three and nine months ended September 30, 2014, the Company recorded an income tax benefit of $7.4 million. The 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 net loss carryforwards and changes in valuation allowance related to tax loss carryforwards. Income tax benefit for the three and nine months ended September 30, 2014 differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to the Company's anticipation of net income in 2014 generated as a result of entering into the Genentech Agreement and other permanent differences.

The valuation allowance for deferred tax assets as of September 30, 2015 and December 31, 2014 was $19.8 million and $14.5 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of September 30, 2015 and December 31, 2014, due to the uncertainty of future recoverability.

As of September 30, 2015, the Company had federal net operating loss carryforwards of $1.9 million and federal research and orphan drug credit carryforwards of $9.3 million. Sections 382 and 383 of the Internal Revenue Code limit a corporation’s ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three-year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change, and any increased liabilities could adversely affect the corporation’s business, results of operations, financial condition and cash flow.

Based on analysis from inception through December 31, 2014, the Company experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. For the year ended December 31, 2014, these ownership changes limited the Company's ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to the respective

ownership changes of NewLink and BPS. Additional ownership changes may have occurred subsequent to December 31, 2014 and may occur in the future as a result of events over which the Company will have little or no control, including purchases and sales of the Company's equity by its 5% stockholders, the emergence of new 5% stockholders, additional equity offerings or redemptions of the Company's stock or certain changes in the ownership of any of the Company's 5% stockholders.

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

8. Net Loss per Common Share

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

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

	Three Months Ended September 30		Nine Months Ended September 30,	
	2015	2014	2015	2014
Historical net loss per share				
Net loss attributable to common stockholders	$(15,906)	$(5,598)	$(18,807)	$(23,997)
Basic and diluted average shares outstanding	28,734,768	27,914,782	28,518,503	27,800,246
Basic and diluted loss per share	$(0.55)	$(0.20)	$(0.66)	$(0.86)

As of September 30, 2015 and 2014, 5,790,468 and 4,889,027, respectively, common equivalent shares of potentially dilutive securities were not included in the calculation of diluted loss per common share because to do so would be anti-dilutive.

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

9. 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.

10. Subsequent Events

On October 1, 2015, the Company announced that the Biomedical Advanced Research and Development Authority (BARDA) of the United States Department of Health and Human Services (HHS) exercised an $18.0 million option on the Company's existing contract to support the scale-up of the manufacturing process relating to its investigational rVSV-ZEBOV GP (Ebola) vaccine candidate.

Table of Contents

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 plans to develop and commercialize our product candidates; our ongoing and planned preclinical studies and clinical trials, including the timing for completion of enrollment and outcome of our Phase 3 clinical trials for our algenpantucel-L cancer immuno-oncology product candidate; the timing of release of the results of interim analyses or other data from ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and other risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" of this Quarterly Report and in our other periodic reports filed from time to time with the Securities and Exchange Commission, or SEC, including our Annual Report on Form 10-K for the year ended December 31, 2014. Our actual results could differ materially from those discussed in our forward-looking statements for many reasons, including those risks. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. Our portfolio includes biologic and small-molecule immuno-oncology product candidates intended to treat a wide range of oncology indications. Our biologic product candidates are based on our proprietary HyperAcute® Cellular Immunotherapy technology, which is designed to stimulate the human immune system. We are in the later stages of development of our HyperAcute Pancreas product candidate, algenpantucel-L, with two Phase 3 clinical trials ongoing, one of which is expected to read out data during 2016. Our additional HyperAcute Cellular Immunotherapy product candidates in clinical development include tergenpumatucel-L or HyperAcute Lung, dorgenmeltucel-L or HyperAcute Melanoma, and product candidates for other potential indications. Our small-molecule product candidates, including inhibitors of the IDO/TDO pathways, are focused on breaking the immune system's tolerance to cancer. 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.

Table of Contents

The chart below summarizes our current HyperAcute Cellular Immunotherapy product candidates and their stages of development.

HyperAcute Cellular Immunotherapy Pipeline

Agent	Target Disease	Design Details	Phase1	Phase 2	Phase 3
Algenpantucel-L	Pancreatic cancer (resected)	IMPRESS: algenpantucel-L + standard of care; randomized	Data expected during 2016		
	Pancreatic cancer (borderline resectable or locally advanced unresectable)	PILLAR: algenpantucel-L + chemotherapy; randomized	Complete enrollment expected in 2015		
Tergenpumatucel-L	NSCLC (advanced or metastatic)	Tergenpumatucel-L vs docetaxel and controlled for follow-on chemotherapy; phase 2b; randomized	Enrolling		
Dorgenmeltucel-L	Melanoma (advanced)	Dorgenmeltucel-L + ipilimumab or PD-1 inhibitors; randomized	Enrolling		
HyperAcute Prostate	Prostate cancer (castrate-resistant)	HyperAcute Prostate: single agent, dose escalation	Enrolled		
HyperAcute Renal	Renal cancer (advanced)	HyperAcute Renal; single agent, dose escalation	Enrolling		

Our HyperAcute Cellular Immunotherapy platform consists of novel biologic product candidates designed to stimulate the patient's immune system to recognize and attack cancer cells. To date, our HyperAcute Cellular Immunotherapy platform product candidates have been administered to more than 700 patients with cancer, either as a monotherapy or in combination with other treatments and have been generally well tolerated with limited grade 3/4 adverse events. 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 a human 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. We believe these unique properties of our HyperAcute Cellular Immunotherapy product candidates have the potential to result in the stimulation of a robust immune response.

Our most advanced program, algenpantucel-L, which utilizes our HyperAcute Cellular Immunotherapy technology, is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (IMmunotherapy for Pancreatic REsectable cancer Survival Study) has completed enrollment of 722 patients with surgically resected pancreatic cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or the FDA. IMPRESS data is expected during 2016. A second Phase 3 trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectable disease), is currently enrolling patients and is expected to complete enrollment before the end of 2015. We initiated these trials based on encouraging Phase 2 data that suggest potential to improve both disease-free and overall survival. Algenpantucel-L has received Fast Track Designation from the FDA for the adjuvant treatment of Stage I/II resected pancreatic adenocarcinoma in combination with adjuvant gemcitabine chemotherapy and Orphan Drug designation from the FDA for the treatment of pancreatic cancer, as well as Orphan Medicinal Product designation from the European Commission for the adjuvant treatment of patients with surgically-resected pancreatic cancer. The primary endpoint for our IMPRESS trial with algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer is overall survival. As determined by the SPA, the first interim analysis was conducted when 222 events (deaths) were reported for the clinical trial, which occurred during the first quarter of 2014. As part of this planned interim analysis, the independent data safety

monitoring committee, or DSMC, met to review available patient data. As anticipated, following its review, the DSMC recommended that the clinical trial should proceed as planned, without modification. The second interim analysis was completed during the second quarter of 2015 following 333 events, which had occurred prior to February 26, 2015. For the second interim analysis, the DSMC reviewed available patient data and recommended the clinical trial proceed without modification to final analysis. We previously announced that concurrent with the second interim analysis, a Kaplan-Meier estimation of overall median survival calculated from the same data set determined that the estimated blended median overall survival in the trial from the time of randomization was 28.5 months for all patients. This compares with a long-standing Kaplan-Meier estimated survival in resected pancreatic cancer of approximately 20 months. Median time from surgery to randomization was approximately 1.5 months. Therefore, median survival from surgery was estimated to be approximately 30 months for all patients in our clinical trial. The clinical trial is powered to show an improvement in overall survival after the anticipated 442 events.

Table of Contents

The chart below summarizes our current IDO pathway inhibitor product candidates and their stages of development.

IDO Pathway Inhibitor Platform

Agent	Target Disease	Design Details	Phase1	Phase 2	Phase 3
Indoximod	Breast cancer (metastatic)	Indoximod + taxane; randomized	Enrolling		
	Prostate cancer (metastatic, castrate-resistant)	Indoximod following sipuleucel-T; randomized	Enrolling		
	Pancreatic cancer (metastatic)	Indoximod + gemcitabine and nab-paclitaxel; phase 1b/2	Enrolling		
	Melanoma (advanced)	Indoximod + ipilimumab or PD-1 inhibitors; phase 2	Enrolling		
	Glioblastoma multiforme	Indoximod + temozolomide; phase 2	Enrolling		
GDC-0919	Solid tumors	GDC-0919			
	Solid tumors	GDC-0919 + PD-L1 inhibitor or anti-OX40	Partnered with Genentech, Inc.		

In addition to our HyperAcute Cellular Immunotherapy platform, 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 drug candidates 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. Recent clinical trials have demonstrated that 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. We have a number of active programs directed at synthesizing inhibitors that are potential anti-cancer compounds and that could function individually or in combination with IDO inhibition.

Our IDO/TDO pathway inhibitors represent a key class of immune checkpoint inhibitors that we believe have the potential to be breakthrough approaches to cancer therapy. In October 2014, we entered into an exclusive worldwide license and collaboration agreement with Genentech, Inc., a member of the Roche Group, or Genentech, for the development and commercialization of GDC-0919, one of our IDO pathway inhibitors, 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 in November 2014. 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 also provides us with funding for support of the research collaboration. We will continue to pursue development activities associated with GDC-0919 in combination with our novel HyperAcute Cellular Immunotherapy platform. We retain the option for co-promotion rights for GDC-0919 and potential next-generation IDO/TDO compounds in the United States.

Our proprietary IDO pathway inhibitor, indoximod, is in multiple Phase 1 and Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic and brain cancers as well as melanoma.

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 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 GP (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

Table of Contents

Merck, Sharp and Dohme Corp., or Merck, to develop and potentially commercialize our rVSV-ZEBOV GP vaccine product candidate. 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. On July 31, 2015, we announced that the international partnership studying the rVSV-ZEBOV GP vaccine candidate in Guinea released interim data suggesting that it is effective against Ebola in a large clinical trial. According to the announcement, the interim results suggest that the vaccine candidate demonstrates efficacy within about 10 days of administration to a person without the infection. The rVSV-ZEBOV GP product candidate will continue to be studied in clinical trials.

We had a net loss of $15.9 million and $18.8 million for the three and nine months ended September 30, 2015, respectively. We expect our losses to increase over the next several years as we advance our product candidates through late-stage clinical trials, pursue regulatory approval of our product candidates, and expand our commercialization activities in anticipation of one or more of our product candidates receiving marketing approval.

On October 25, 2011, we filed a Certificate of Amendment of our Restated Certificate of Incorporation with the Secretary of State of Delaware effecting a 2.1-for-one reverse split of our common stock. All share and per share amounts have been retroactively restated where applicable in the accompanying financial statements and notes for all periods presented.

Founded in 1999 and headquartered in Ames, Iowa, we have a clinical, research and development staff that is developing our pipeline of product candidates for potential commercialization. We have established offices in Austin, Texas, where we intend to build our own commercial organization through which we intend to market our oncology products in the United States, and in Devens, Massachusetts, where we manage the development of and strategic relationships relating to our Ebola vaccine product candidate. Finally, we have built a distribution facility in Ankeny, Iowa for the distribution of algenpantucel-L, if it is approved, and other potential products we may commercialize. Outside the United States we will either commercialize and distribute approved products or seek commercialization and distribution collaborators for our product candidates as we have done with Merck in the case of our Ebola vaccine product candidate.

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, 2014, discusses our most critical accounting policies. Since December 31, 2014, there have been no material changes in the critical accounting policies discussed in our 2014 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, 2015 and 2014

Revenues. Revenues for the three months ended September 30, 2015 were $14.2 million, increasing from $2.8 million for the same period in 2014. The increase in revenue of $11.4 million was due to an increase of $10.6 million in grant revenue earned under various government contracts and an increase of $844,000 in licensing and collaboration revenue earned under our licensing and collaboration agreements.

Table of Contents

Research and Development Expenses. Research and development expenses for the three months ended September 30, 2015 were $22.5 million, increasing from $10.9 million for the same period in 2014. Of the $11.6 million increase, $8.6 million was due to costs related to the Ebola vaccine product candidate, outside clinical and other expenses, contract development costs for GDC-0919, contract manufacturing costs for indoximod, consulting fees, and direct development expenses for our clinical trial activities. There was also a $1.6 million increase in personnel-related expenses due to increased staffing levels, and a $1.4 million increase in supplies.

General and Administrative Expenses. General and administrative expenses for the three months ended September 30, 2015 were $7.4 million, increasing from $4.9 million for the same period in 2014. The $2.5 million increase was due to a $1.4 million increase in consulting, legal and licensing fees, a $1.0 million increase in personnel-related expenses due to increased staffing levels, share-based compensation expense, and compensation increases and a $100,000 increase in supplies.

Income Tax Benefit (Expense). The income tax expense for the three months ended September 30, 2015 was $160,000, compared to an income tax benefit of $7.4 million for the same period in 2014. The change is primarily due to the difference in the estimated effective annual tax rate between 2014 and 2015.

Net Loss. The net loss for the three months ended September 30, 2015 was $15.9 million compared to $5.6 million for the same period in 2014. The $10.3 million increase in the net loss was due to a $14.1 million increase in operating expenses offset by a $11.4 million increase in revenues and a $7.6 million decrease in income tax benefit as discussed above. The basic and diluted weighted average common shares outstanding for the three months ended September 30, 2015 were 28,734,768, resulting in a loss per share of $0.55, as compared to 27,914,782 and a $0.20 loss per share for the three months ended September 30, 2014.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Revenues. Revenues for the nine months ended September 30, 2015 were $60.8 million, increasing from $3.3 million for the same period in 2014. The increase in revenue of $57.5 million was due to an increase of $34.6 million in licensing and collaboration revenue, primarily due to a one-time $20.0 million non-refundable milestone payment in February 2015, and a $22.9 million increase in grant revenue under various government contracts.

Research and Development Expenses. Research and development expenses for the nine months ended September 30, 2015 were $56.6 million, increasing from $23.8 million for the same period in 2014. Of the $32.8 million increase, $23.0 million was due to expenses related to the Ebola vaccine product candidate, outside clinical and other expenses, including contract manufacturing costs for indoximod, consulting fees, and direct development expenses for our clinical trial activities. There was also a $7.0 million increase in personnel-related expenses due to increased staffing levels and compensation increases, which includes a $2.4 million increase in share-based compensation expense recognized in connection with the departure of an executive. The remaining increase of $2.8 million was for supplies.

General and Administrative Expenses. General and administrative expenses for the nine months ended September 30, 2015 were $23.0 million, increasing from $11.0 million for the same period in 2014. The $12.0 million increase was due to a $6.3 million increase in consulting, legal and licensing fees, accompanied by a $5.3 million increase in personnel-related expenses due to increased staffing levels, share-based compensation expense, and compensation increases and a $400,000 increase in supplies.

Income Tax Benefit (Expense). Income tax expense for the nine months ended September 30, 2015 was $0, compared to an income tax benefit of $7.4 million for the same period in 2014. The change is primarily due to the difference in the estimated effective annual tax rate between 2014 and 2015.

Net Loss. The net loss for the nine months ended September 30, 2015 was $18.8 million, compared to $24.0 million for the same period in 2014. The $5.2 million decrease was due to the changes in revenue earned, research and development and general and administrative expenses and income tax expense discussed above. The basic and diluted weighted-average common shares outstanding for the nine months ended September 30, 2015 were 28,518,503, resulting in a loss per share of $0.66, as compared to 27,800,246 and a $0.86 loss per share for the nine months ended September 30, 2014.

Liquidity and Capital Resources

We raised an aggregate of $76.3 million in proceeds, net of offering costs, from the issuance of convertible preferred stock prior to our IPO, at which time all of our then-outstanding preferred stock converted to common stock. We raised net proceeds of $37.6 million from our IPO. In the years following our IPO, we raised net proceeds of $49.0 million in a follow-on offering in 2013, and we have raised an additional $58.7 million in net proceeds from the ATM Offering through March 31, 2015 ($17.5 million in 2013, $27.7 million in 2014, and $13.6 million year to date in 2015).

Table of Contents

We received an upfront payment of $150.0 million under the Genentech Agreement in October 2014, and an upfront payment of $30.0 million in November 2014 as well as a $20.0 million milestone payment in February 2015 under the Merck Agreement.

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,	
	2015	2014
Net cash used in operating activities	$(15,735)	$(21,609)
Net cash provided by (used in) investing activities	5,727	(17,731)
Net cash provided by financing activities	16,745	29,119
Net increase (decrease) in cash and cash equivalents	$6,737	$(10,221)

For the nine months ended September 30, 2015 and 2014, we used cash of $15.7 million and $21.6 million, respectively, for our operating activities. For the nine months ended September 30, 2015, 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.

For the nine months ended September 30, 2015 and 2014, our investing activities provided cash of $5.7 million, and used cash of $17.7 million, respectively. 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. The cash used by investing activities in the nine months ended September 30, 2014 was due to the purchases of certificates of deposit for $16.4 million and $1.3 million in purchases of property and equipment.

For the nine months ended September 30, 2015 and 2014, our financing activities provided $16.7 million and $29.1 million, respectively. The cash provided by financing activities in the nine months ended September 30, 2015 was primarily due to the sale and issuance of common stock for net proceeds of $17.2 million, offset by repurchase of common stock of $341,000 and net payments on long-term obligations and notes payable of $144,000. The cash provided by financing activities in the nine months ended September 30, 2014 was primarily due to the sale and issuance of common stock for net proceeds of $29.4 million, offset by the repurchase of common stock of $222,000 and net payments on long-term obligations and notes payable of $41,000.

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses related to the research and development of our HyperAcute Cellular Immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure.

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, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biopharmaceutical products, we are unable to determine the exact amounts of our working capital requirements. Our

future funding requirements will depend on many factors, including, but not limited to:

- 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;

Table of Contents

- 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 our existing or future products, if any; and
- payments received under any future strategic collaborations.

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, 2014.

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, 2015 and December 31, 2014, we had cash and cash equivalents and certificates of deposit of $200.4 million and $202.8 million, respectively, consisting of bank certificates of deposit. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of United States interest rates, particularly because our investments are in certificates of deposit. Our certificates of deposit are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We expect to have the ability to hold our certificates of deposit until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation required by the Securities Exchange Act of 1934, as amended, or the Exchange Act, under the supervision and with the participation of our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of September 30, 2015. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of September 30, 2015, 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.

Table of Contents

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

Our near-term prospects are highly dependent on algenpantucel-L for patients with surgically resected pancreatic cancer. If we fail to complete clinical trials, fail to demonstrate safety and efficacy in those clinical trials, fail to obtain regulatory approval or fail to successfully commercialize algenpantucel-L, our business would be harmed and the value of our securities would likely decline.

We must be evaluated in light of the uncertainties and complexities affecting a development stage biopharmaceutical company. We have not completed clinical development for any of our product candidates. Our most advanced oncology product candidate is algenpantucel-L. The FDA must approve algenpantucel-L before it can be marketed or sold. Our ability to obtain FDA approval of algenpantucel-L depends on, among other things, completion of one or both of our Phase 3 clinical trials, whether our Phase 3 clinical trials of algenpantucel-L demonstrate statistically significant achievement of the applicable clinical trial endpoints with an acceptable safety and tolerability profile and whether the FDA agrees that the data from either of our Phase 3 clinical trials of algenpantucel-L are sufficient to support approval. In addition, there are multiple methods of statistical analysis that could be used to evaluate the data from our algenpantucel-L IMPRESS Phase 3 clinical trial and other clinical trials, and the methods that we use, or that the FDA uses or permits us to use, may demonstrate lower, or no, statistical significance in achieving the applicable clinical trial endpoints, or may require an extended period of time to demonstrate statistical significance, if at all, as compared to other methods of statistical analysis that we could use.

The final results of our Phase 3 clinical trials of algenpantucel-L may not meet the FDA’s requirements to approve the product for marketing, and the FDA may otherwise determine that our manufacturing processes, facilities or raw materials are insufficient to warrant approval. We may need to conduct more clinical trials than we currently anticipate. Furthermore, even if we do receive FDA approval, we may not be successful in commercializing algenpantucel-L. If any of these events occur, our business could be materially harmed and the value of our common stock would likely decline.

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

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

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

Prior clinical trial program designs and results are not necessarily predictive of future clinical trial designs or results. Initial results may not be confirmed upon full analysis of the detailed results of a trial. Product candidates in

later-stage clinical

trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials with acceptable endpoints.

In particular, there have been no control groups in our clinical trials completed to date. While comparisons to results from other reported clinical trials can assist in predicting the potential efficacy of algenpantucel-L, there are many factors that affect the outcome for patients in clinical trials, some of which are not apparent in published reports, and results from two different trials cannot always be reliably compared. As a result, we are studying algenpantucel-L in combination with the current standard-of-care in direct comparison to the current standard-of-care alone in the same trial and will need to show a statistically significant benefit when added to the current standard-of-care in order for algenpantucel-L to be approved as a marketable drug. Patients in our Phase 3 clinical trial who do not receive algenpantucel-L may not have results similar to patients studied in the other clinical trials we have used for comparison to our Phase 2 clinical trials. If the patients in our Phase 3 clinical trial who receive standard-of-care without algenpantucel-L have results that are better than the results predicted by the other large clinical trials, we may not demonstrate a sufficient benefit from algenpantucel-L to allow or convince the FDA to approve it for marketing.

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

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

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

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

Our SPA with the FDA relating to our algenpantucel-L IMPRESS Phase 3 clinical trial does not guarantee any particular outcome from regulatory review of the trial or the product candidate, including any regulatory approval.

The protocol for our algenpantucel-L IMPRESS Phase 3 clinical trial was reviewed by the FDA under its SPA process, which allows for FDA evaluation of a clinical trial protocol intended to form the primary basis of an efficacy claim in support of a Biologics License Application, or BLA, and provides an agreement that the clinical trial design, including trial size, clinical endpoints and/or data analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. However, the SPA agreement is not a guarantee of approval, and any methods of data analysis that we may propose to use that are not specifically set forth in the SPA may be rejected by the FDA. The FDA retains the right to require additional Phase 3 testing, and we cannot be certain that the design of, or data collected from, the IMPRESS Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of algenpantucel-L for the treatment of patients with surgically resected pancreatic cancer, or otherwise be sufficient to support FDA or any foreign regulatory approval. In addition, the survival rates, duration of response and safety profile required to support FDA approval are not specified in the IMPRESS Phase 3 clinical trial protocol and will be subject to FDA review. Further, the SPA agreement is not binding on the FDA if public health concerns unrecognized at the time the SPA agreement was entered into become evident, other new

scientific concerns regarding product safety or efficacy arise, or if we fail to comply with the agreed-upon trial protocols. In addition, the SPA agreement may be changed by us or the FDA on written agreement of both parties, and the FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from the IMPRESS Phase 3 clinical trial. As a result, we do not know how the FDA will interpret the parties' respective commitments under the

SPA agreement, how it will interpret the data and results from the IMPRESS Phase 3 clinical trial, how it will view our analysis of such data and results or whether algenpantucel-L will receive any regulatory approvals as a result of the IMPRESS Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer.

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

Because we have limited financial and managerial resources, we must focus on research programs and product candidates for the specific indications that we believe are the most scientifically and commercially promising. As a result, we have in the past determined to let certain of our development projects remain idle, including by allowing Investigational New Drug applications to lapse into inactive status, and we may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. We are currently allocating significant resources to the development of an Ebola vaccine product candidate in accordance with our obligations under the Merck Agreement, and these efforts may ultimately prove unsuccessful or unprofitable and may divert our resources from the development and commercialization of our other product candidates. 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;
- 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;
- 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.

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;
- in the case of Ebola vaccine product candidate trials, changes in media coverage of the recent Ebola epidemic;
- 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.

26

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

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

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

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

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

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

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

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

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

- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- failure to demonstrate a benefit from using a drug;
- the quality or stability of the product candidate may fall below acceptable standards; or

- insufficient quantities of the product candidate to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to Institutional Review Boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our HyperAcute Cellular Immunotherapy product candidates, indoximod 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.

Indoximod, our proprietary IDO pathway inhibitor product candidate, has been studied in two Phase 1b/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying indoximod in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of dorgenmeltucel-L (HyperAcute Melanoma) 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.

We have received Fast Track and Orphan Drug Designations for algenpantucel-L and may seek one or more of these or other special designations from regulatory authorities for our other product candidates. These designations may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

Sponsors of biologic or pharmaceutical product candidates may seek designations from the FDA designed to accelerate the FDA’s review and approval of marketing applications. For example, we have received Fast Track Designation for algenpantucel-L. Fast Track Designation may be granted to a drug intended for treatment of a serious or life-threatening disease or condition that has potential to address unmet medical needs for the disease or condition. The key benefits of Fast Track Designation include potential eligibility for priority review, rolling review (submission of portions of an application before the complete marketing application is submitted), and accelerated approval, if relevant criteria are met. Under the accelerated approval program, the FDA may approve a product candidate on the

basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies

or completion of ongoing studies after marketing approval are generally required to verify the product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

The FDA has broad discretion over whether or not to grant these designations, so even if we believe a particular product candidate is eligible for a particular designation, we cannot assure you that the FDA would decide to grant it. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree and instead determine not to make such a designation. In any event, the receipt of a particular designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. Further, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from a clinical development program.

We have also received Orphan Drug Designation for algenpantucel-L. The FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population of greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, or the EU, the European Medicines Agency's, or the EMA's, Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition when the prevalence of the condition is not more than five in 10,000 persons in the EU or when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the product. Additionally, there must be no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have orphan drug designation for algenpantucel-L in the United States and EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing biologic and pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a competing product can be approved for a different indication. Even after an orphan drug is approved, the FDA or EMA can subsequently approve another drug with the same active moiety for the same condition if the FDA or EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care.

Even if approved, the HyperAcute Cellular Immunotherapy product candidates, indoximod, GDC-0919, 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 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 plan to increase our manufacturing capacity, which may include negotiating and entering into arrangements for third-party contract manufacturing for some or all of our commercial manufacturing requirements. We plan to seek FDA approval for our production process in connection with our BLA for algenpantucel-L. Should we not receive timely approval of our production process, our ability to produce the immuno-oncology products following regulatory approval for sale could be delayed, which would further delay the period of time when we would be able to generate revenues from the sale of such products, if we are even able to generate revenues at all.

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

We do not have a sales organization and have no experience in the sales and distribution of pharmaceutical products. There are risks involved with establishing our own sales capabilities and increasing our marketing capabilities, as well as entering into arrangements with third parties to perform these services. Developing an internal sales force is expensive and time consuming and could delay any product launch. On the other hand, if we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us could potentially be lower than if we market and sell 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 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 towards commercialization of our product candidates, and because of the numerous risks and uncertainties involved with establishing those capabilities, we are unable to predict when, if ever, we will establish our own sales, marketing and distribution capabilities. If we are not able to collaborate with third parties and are unsuccessful in recruiting sales, marketing and distribution personnel or in building the necessary infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition.

Failure to attract and retain key personnel could impede our ability to develop our products and to obtain new collaborations or other sources of funding.

Because of the specialized scientific nature of our business, our success is highly dependent upon our ability to attract and retain qualified scientific and technical personnel, consultants and advisors. We are highly dependent on the principal members of our scientific and management staff, particularly Dr. Charles J. Link, Jr. and Dr. Nicholas N. Vahanian. The loss of services by either of these leaders might significantly delay or prevent the achievement of our research, development, and

30

business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit a significant number of additional personnel in order to achieve our operating goals. In order to pursue product development and marketing and sales activities, if any, we will need to hire additional qualified scientific personnel to perform research and development, as well as personnel with expertise in clinical testing, government regulation, manufacturing, marketing and sales. We also rely on consultants and advisors to assist in formulating our research and development strategy and adhering to complex regulatory requirements. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on acceptable terms, if at all. If the personnel who have contingently agreed to join us choose, not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our most significant facilities are located in Iowa, which may make attracting and retaining qualified scientific and technical personnel from outside of Iowa difficult. The failure to attract and retain qualified personnel, consultants and advisors could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing Activities

We have never manufactured our product candidates at commercial scale, and there can be no assurance that such products can be manufactured in compliance with regulations at a cost or in quantities necessary to make them commercially viable.

We have no experience in commercial-scale manufacturing, the management of large-scale information technology systems or the management of a large-scale distribution system. In June 2014, we granted WuXi AppTec Inc., or WuXi, a non-exclusive right to use certain of our starting materials and confidential information for the commercial manufacturing of cell material for the production of algenpantucel-L, or the WuXi Agreement. We will incur significant expense under the WuXi Agreement or under similar commercial manufacturing arrangements, and our commercial manufacturing programs may not result in the manufacture of algenpantucel-L to the required quality standards or in quantities or at a cost that allows any future commercial sales to be profitable or commercially viable for many reasons, including the following:

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

We may develop additional or alternative manufacturing capacity by expanding our current facilities, by entering into additional third-party contract manufacturing arrangements, or by some combination of the foregoing. Expanding our current facilities would require substantial additional funds, and we would need to hire and train significant numbers of qualified employees to staff these facilities. We may not be able to develop commercial-scale manufacturing

facilities that are sufficient to produce materials for additional later-stage clinical trials or commercial use. Contracting for additional third-party commercial manufacturing would require expertise and qualified personnel to manage the added complexity of such additional relationships and regulatory compliance at multiple manufacturing sites operated by different third-parties and may further increase our expenses related to, and decrease our direct control over, procuring a sufficient supply of our product candidates for commercial sale.

If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with WuXi or other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of each BLA and each New Drug Application, or NDA, on a timely basis and must adhere to Good Laboratory Practice, or GLP, and current Good Manufacturing Practice, or cGMP, regulations enforced by the FDA through its facilities inspection program. If these facilities cannot pass a pre-approval plant inspection, the FDA approval of the products will not be granted.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our products. All entities involved in the preparation of a therapeutic drug for clinical trials or commercial sale, including 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 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, including algenpantucel-L, for commercial sale, if any are approved for sale. In addition, we currently rely on contract manufacturers for supply of our Ebola vaccine product candidate for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of antigen, components of HyperAcute Cellular Immunotherapy product candidates, indoximod, GDC-0919 or our Ebola vaccine product candidate, or finished products. This could delay or reduce commercial sales and materially harm

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

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 and would cause us to seek additional third-party manufacturing contracts, thereby increasing our development costs. We may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

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

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, or to supply the component at quantities insufficient for commercial sale, we may need to utilize an alternative manufacturer. If we utilize an alternative manufacturer, we may be required to demonstrate comparability

of the drug product before releasing the product for clinical use. The loss of our current supplier could result in manufacturing delays for the component substitution, and we may need to accept changes in terms or price from our existing supplier in order to avoid such delays.

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

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

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

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

Risks Relating to Regulation of Our Industry

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

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

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, 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 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.
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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, enacted as part of the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, 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 busines and results of operations. In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. We expect to face pricing pressure globally from managed care organizations, institutions and government agencies and programs, which could negatively affect the sales and profit margins for any of our product candidates that may be approved for marketing.

In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In March 2010, the PPACA was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;
- a licensure framework for follow-on biologic products, also known as biosimilars;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

At this time, the full effect that the PPACA would have on our business remains unclear. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies. Other legislative changes have been proposed and adopted in the United States since PPACA including reductions of Medicare payments to providers. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing

pressures. 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.

Algenpantucel-L and certain other of our product candidates may be regulated as biological products, or biologics, which may subject them to competition sooner than anticipated.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the PPACA, 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. We believe that if the

FDA approves a BLA for algenpantucel-L, algenpantucel-L should qualify for this 12-year period of market exclusivity, known as reference product exclusivity, such that 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 algenpantucel-L to be eligible for reference product exclusivity, potentially

creating the opportunity for competition sooner than anticipated. In addition, even if algenpantucel-L 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 expect to incur net losses in 2015 and to continue to incur increasing 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 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 do not expect to be profitable in the year ending December 31, 2015. 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. In addition, we have incurred significant net losses in each year since our inception prior to the year ended December 31, 2014, including net losses of $31.2 million and $23.3 million for the years ended December 31, 2013 and 2012, respectively. Despite our net income for the year ended December 31, 2014, we had an accumulated deficit of $58.8 million as of September 30, 2015. Our losses have resulted principally from costs incurred in our research activities. We anticipate that our operating losses will substantially increase over the next several years as we expand 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, build commercial capabilities, develop our pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents and certificates of deposit will allow us to fund our operating plan through the end of 2016, although not through commercialization and launch of revenue-producing products. However, our operating plan may change as a result of factors currently unknown to us. There can be no assurance that our revenue and expense forecasts will prove to be accurate, and any change in the foregoing assumptions could require us to obtain additional financing earlier than anticipated. There is a risk of delay or failure at any stage of developing a product candidate, and the time required and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs.

We are party to license agreements with various parties pursuant to which we have obtained licenses to certain patents, patent applications and other intellectual property related to our product candidates and product development efforts. Pursuant to most of these license agreements, we are obligated to make aggregate payments ranging from approximately $200,000 to $2.8 million per license (and in some cases, for each product candidate in such license) upon achievement of development and regulatory approval milestones specified in the applicable license. The timing of our achievement of these events and corresponding milestone payments to our licensors is subject to factors relating to the clinical and regulatory development and commercialization of our product candidates, many of which are beyond our control. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization or marketing efforts or seek funds to meet these obligations on terms unfavorable to us.

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

would otherwise seek to develop or commercialize ourselves.

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

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

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

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

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

As a result of our profitability for the year ended December 31, 2014, we were subject to income taxes, and we may become subject to income taxes in future years in the United States or foreign jurisdictions. Our effective income tax rate, as well as our relative domestic and international tax liabilities, will depend in part on the allocation of any future income among different jurisdictions. In addition, various factors may have favorable or unfavorable effects on our effective income tax rate in individual jurisdictions or in the aggregate. These factors include whether tax authorities agree with our interpretations of existing tax laws, any required accounting for stock options and other share-based compensation, changes in tax laws and rates, our future levels of research and development spending, changes in accounting standards, changes in the mix of any future earnings in the various tax jurisdictions in which we may operate, the outcome of any examinations by the U.S. Internal Revenue Service or other tax authorities, the accuracy of our estimates for unrecognized tax benefits and realization of deferred tax assets and changes in overall levels of pre-tax earnings. The effect on our income tax liabilities resulting from the above-mentioned factors or other factors could have a material adverse effect on our results of operations.

Risks Relating to Competition

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

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

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

We may face competition based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price and patent position. There can

be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

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

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. The competitors of which we are aware that have initiated a Phase 3 clinical trial or have obtained marketing approval for a potentially competitive drug to our lead product candidate, algenpantucel-L for the adjuvant treatment of patients with surgically resected pancreatic cancer, include Astra-Zeneca, Celgene Corporation, Incyte Corporation, Merrimack Pharmaceuticals, and Threshold Pharmaceuticals. 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 drug 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 drug 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 drug candidates, we also will compete with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we currently have limited experience. We also face competition from pharmaceutical and biotechnology companies, academic institutions, government agencies and private research organizations in recruiting and retaining highly qualified scientific personnel and consultants and in the development and acquisition of technologies. Moreover, technology controlled by third parties that may be advantageous to our business may be acquired or licensed by our competitors, thereby preventing us from obtaining technology on commercially reasonable terms, if at all. We will also compete for the services of third parties that may have already developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies to target the diseases on which we have focused both inside and outside of the United States.

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

Research and discoveries by others may result in breakthroughs that render our HyperAcute Cellular Immunotherapy product candidates, indoximod, GDC-0919 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, there are competitive efforts by public and private entities to develop an Ebola vaccine as fast as possible, including by GlaxoSmithKline. Those other entities may develop Ebola vaccines that are more effective than any we may develop in collaboration with Merck, or may develop an Ebola vaccine at a lower cost or earlier than we or Merck are able to develop any Ebola vaccine, or they may be more successful at commercializing an Ebola 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 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.

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.

43

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 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, 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 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 may become involved in securities class-action litigation that could divert management’s attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations as well as broad range of other factors, including the realization of any of the risks described in the “Risk Factor,” section of this Quarterly Report on Form 10-Q, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally

experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management’s attention and resources,

which could adversely affect our business. Any adverse determination in any such litigation, or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Risks Related to Ownership of Our Common Stock

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

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

- new products, product candidates or new uses for existing products introduced or announced by our strategic collaborators, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, including our Phase 3 IMPRESS clinical trial of algenpantucel-L, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including 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. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

48

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, 2015, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 45.6% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after September 30, 2015. 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 Stock 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;
- 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, 2014, we experienced Section 382 ownership changes in September 2001 and March 2003, and BPS experienced Section 382 ownership changes in January 2006 and January 2011. These ownership changes limited our ability to utilize federal net operating loss carryforwards and certain other tax attributes that accrued prior to the respective ownership changes of us and our subsidiaries and may continue to limit our ability to utilize such attributes in the future.

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

stockholders.

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

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

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

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

Table of Contents

ITEM 1. LEGAL PROCEEDINGS

None.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Table of Contents

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 6, 2015

By: /s/ John B. Henneman, III
John B. Henneman, III
Chief Financial Officer and Secretary
(Principal Financial Officer)
Date: November 6, 2015

Table of Contents

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

Exhibit Number		Description	Incorporated By Reference			Filed Herewith
			Form	Filing Date	Number	
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Certificate of Amendment to Restated Certificate of Incorporation filed on May 10, 2013	8-K	5/14/2013	3.1	
3.3		Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1		Form of the Registrant's Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2		Reference is made to Exhibits 3.1, 3.2 and 3.3 hereof				
4.3		Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company's capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
31.1		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

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.