NEWLINK GENETICS CORP
Form 10-Q
May 08, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

ý Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.
For the quarterly period ended March 31, 2014.
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 May 6, 2014, there were 27,874,204 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

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PART I

NewLink Genetics Corporation
and Subsidiaries
(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$83,713	$61,291
Certificates of deposit	249	249
Prepaid expenses	679	773
State research and development credit receivable	417	329
Other receivables	251	1,328
Total current assets	85,309	63,970
Leasehold improvements and equipment:		
Leasehold improvements	5,576	5,588
Computer equipment	1,151	1,133
Lab equipment	3,821	3,724
Total leasehold improvements and equipment	10,548	10,445
Less accumulated depreciation and amortization	(4,114)	(3,858)
Leasehold improvements and equipment, net	6,434	6,587
Total assets	$91,743	$70,557

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	March 31, 2014	December 31, 2013
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$972	$612
Accrued expenses	2,381	2,861
Income taxes payable	5	130
Current portion of deferred rent	84	84
Current portion of long term debt and obligations under capital leases	190	189
Total current liabilities	3,632	3,876
Long-term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	986	1,033
Deferred rent, excluding current portion	1,300	1,321
Total long-term liabilities	8,286	8,354
Total liabilities	11,918	12,230
Commitments and contingencies		
Stockholders' Equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at March 31, 2014 and December 31, 2013; issued and outstanding shares — 0 at March 31, 2014 and December 31, 2013	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at March 31, 2014 and December 31, 2013; issued shares — 27,870,883 and outstanding shares — 27,862,390 at March 31, 2014, and issued and outstanding shares — 26,573,023 at December 31, 2013	279	266
Additional paid-in capital	224,941	194,038
Treasury stock, at cost: 8,493 shares at March 31, 2014	(182)	—
Deficit accumulated during the development stage	(145,213)	(135,977)
Total stockholders' equity	79,825	58,327
Total liabilities and stockholders' equity	$91,743	$70,557

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
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(A Development Stage Enterprise)

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

	Three Months Ended March 31,		Cumulative from June 4, 1999 (inception) through March 31,
	2014	2013	2014
Grant revenue	$334	$302	$8,831
Operating expenses:			
Research and development	6,387	6,343	107,256
General and administrative	3,251	2,001	49,715
Total operating expenses	9,638	8,344	156,971
Loss from operations	(9,304)	(8,042)	(148,140)
Other income and expense:			
Miscellaneous income	50	114	482
Forgiveness of debt	—	—	449
Interest income	23	2	1,802
Interest expense	(5)	(8)	(219)
Other income (expense), net	68	108	2,514
Net loss before taxes	(9,236)	(7,934)	(145,626)
Income tax expense	—	—	(130)
Net loss	(9,236)	(7,934)	(145,756)
Less net loss attributable to noncontrolling interest	—	—	583
Net loss attributable to NewLink	$(9,236)	$(7,934)	$(145,173)
Net loss per common share, basic and diluted	$(0.33)	$(0.33)	
Weighted-average common shares outstanding, basic and diluted	27,605,910	23,860,469	

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
and Subsidiaries
(A Development Stage Enterprise)

Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(In thousands, except share and per share data)

	Common Stock					
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Treasury Stock	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance at December 31, 2013	26,573,023	$266	$194,038	$—	$ (135,977)	$ 58,327
Share-based compensation	—	—	2,105	—	—	2,105
Exercise of stock options	280,643	3	1,234	—	—	1,237
Issuance of common stock under the ATM offering (net of offering costs of $712, January and February 2014)	1,017,217	10	27,564	—	—	27,574
Shares withheld for minimum tax withholding (January 2, 2014)	(8,493)	—	—	(182)	—	(182)
Net loss	—	—	—	—	(9,236)	(9,236)
Balance at March 31, 2014	27,862,390	$279	$224,941	$(182)	$ (145,213)	$ 79,825

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,		Cumulative from June 4, 1999 (inception) through March 31,
	2014	2013	2014
Cash Flows From Development Activities			
Net loss	$(9,236)	$(7,934)	$(145,756)
Adjustments to reconcile net loss to net cash used in development activities:			
Share-based compensation	2,105	966	15,014
Depreciation and amortization	256	212	4,896
Loss on sale of fixed assets	—	—	40
In-process research and development expenses	—	—	1,629
Forgiveness of debt	—	—	(449)
Forgiveness of notes receivable from related parties	—	—	350
Changes in operating assets and liabilities:			
Prepaid expenses	94	250	(679)
State research and development credit receivable	(88)	(85)	(417)
Other receivables	1,077	(261)	(251)
Accounts payable	351	(106)	(268)
Income taxes payable	(125)	—	5
Accrued expenses and deferred rent	(501)	335	3,765
Net cash used in development activities	(6,067)	(6,623)	(122,121)
Cash Flows From Investing Activities			
Purchase of certificates of deposit	—	—	(13,531)
Sale of certificates of deposit	—	747	13,282
Notes receivable from related parties	—	—	(350)
Purchase of equipment	(93)	(62)	(9,571)
Proceeds on sale of equipment	—	—	50
Cash paid for OncoRx	—	—	(120)
Net cash (used in) provided by investing activities	(93)	685	(10,240)
Cash Flows From Financing Activities			
Cash received from noncontrolling interest investment	—	—	3,479
Issuance of common stock, net of offering costs	28,811	49,035	138,471
Repurchase of common stock	(182)	—	(687)
Proceeds from preferred stock	—	—	67,743
Proceeds from notes payable	—	—	8,215
Principal payments on notes payable	(38)	(37)	(663)
Payments under capital lease obligations	(9)	(32)	(484)
Net cash provided by financing activities	28,582	48,966	216,074
Net increase in cash and cash equivalents	22,422	43,028	83,713

Cash and cash equivalents at beginning of period	61,291	20,250	—
Cash and cash equivalents at end of period	$83,713	$63,278	$83,713
Supplemental disclosure of cash flows information:			
Cash paid for interest	$4	$8	$180
Noncash financing and investing activities:			
Accretion on redeemable preferred stock	—	—	113
Purchased leasehold improvements and equipment in accounts payable	10	9	10
Common stock issued to shareholders of OncoRx as part of acquisition	—	—	1,654
Issuance of common stock dividend to Series AA preferred shareholders	—	—	6
Assets acquired under capital lease	—	—	596
Reduction of IPO offering costs	—	—	158

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation and Subsidiaries
(A Development Stage Enterprise)
Notes to Condensed Consolidated Financial Statements
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1. Description of Business and Development Stage Activities

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 of 2000, which primarily consist of research and development.

In 2005, NewLink created a wholly 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. Subsequent to its creation, certain interests in BPS were sold to minority shareholders. 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 subsidiary, NewLink International (NI). In 2014, NewLink created another subsidiary, NewLink Global (NG). NewLink plans to conduct all or a portion of its operations outside of the United States through NI and NG.

NewLink and its subsidiaries (the Company) are development stage enterprises and are devoting substantially all of their efforts toward research and development. The Company has never earned revenue from sales of its drugs under development. The Company incurred a net loss of $9.2 million for the three months ended March 31, 2014, and from June 4, 1999 (inception) through March 31, 2014 has generated a cumulative deficit of $145.2 million. The Company has managed its liquidity needs during its development stage to date through a series of capital market transactions. On November 16, 2011, the Company completed its initial public offering (IPO) of common stock pursuant to a Registration Statement on Form S-1 that was declared effective on November 10, 2011. The Company sold 6,200,000 shares of common stock at a price of $7.00 per share raising a total of $37.6 million in net proceeds after underwriting discounts and commissions of $3.0 million and offering expenses of $2.9 million. Costs directly associated with the IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount recorded in additional paid-in capital. Upon the closing of the IPO, 14,270,113 shares of the Company’s convertible preferred stock automatically converted into10,719,353 shares of common stock, which also reflected conversion price adjustments to our preferred stock. On February 4, 2013, the Company completed a follow-on offering of its common stock. The Company sold 4,600,000 shares of common stock at a price of $11.40 per share raising a total of $49.0 million in net proceeds.

NewLink entered into a sales agreement with Cantor Fitzgerald & Co., dated as of September 5, 2013, under which NewLink may sell up to $60.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the ATM Offering). Any such sales would be effected pursuant to its registration statement on Form S-3 (333-185721), declared effective by the SEC on January 4, 2013. As of March 31, 2014, the Company had sold 1,833,838 shares of common stock under the ATM Offering, raising a total of $45.0 million in net proceeds. During the years ended December 31, 2013 and 2012, the Company received equity financing of $67.2 million and $1.3 million, respectively, through common stock offerings. Subsequent to March 31, 2014, the Company sold no additional shares of common stock under the follow-on offering or the ATM Offering.

The accompanying financial statements as of March 31, 2014 and for the three months then ended have been prepared assuming the Company will continue as a going concern. As noted above, 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 $45.0 million in net proceeds from the ATM Offering prior to March 31, 2014. The Company's cash and cash equivalents after these offerings are expected to be adequate to satisfy the Company's liquidity requirements well into 2015, 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.

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NewLink Genetics Corporation and Subsidiaries
(A Development Stage Enterprise)
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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 (SEC), without audit, and, in management's opinion, reflect all adjustments necessary to present fairly the Company's interim 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 financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2013, 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 2013. 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.

(b) Principles of Consolidation

The 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

The fair values of cash and cash equivalents, certificates of deposit, receivables, and accounts payable, which are recorded at cost, approximate 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 $1.2 million and $1.2 million as of March 31, 2014 and December 31, 2013, respectively, and was determined using Level 3 inputs. The Company is unable to estimate the fair value of the royalty obligation because the timing and receipt of payments 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 cash equivalents, such as money market funds, or certificates of deposit.

4. Common Stock Equity Incentive Plan

In April 2000, the stockholders approved the Company's 2000 Equity Incentive Plan (the "2000 Plan"), and in July 2009, the stockholders approved the Company's 2009 Equity Incentive Plan (the "2009 Plan"). Following the approval of the 2009 Plan, 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. Shares are added to the reserve of shares available for issuance pursuant to an "evergreen provision" on January 1 of each year, from 2012 to (and including) 2019, in an amount equal to 4% of the total number of shares

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of Common Stock outstanding on December 31 of the preceding calendar year. As of March 31, 2014, there were 6,799,854 shares of common stock authorized for the 2009 plan and 1,074,909 shares remained available for issuance. On January 7, 2011, stockholders authorized an increase of 714,286 shares of common stock available for issuance under the 2009 Plan. On January 1, 2012 an additional 823,649 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2013, an additional 838,375 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan. On January 1, 2014 an additional 1,066,340 shares of common stock were added to the shares reserved for future issuance under the 2009 Plan.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Award Plan (Directors' Plan), which became effective on November 10, 2011, 238,095 shares of common stock were reserved for future issuance. On May 9, 2013 an additional 161,905 shares of common stock were added to the shares reserved for future issuance under the Directors' Plan. As of March 31, 2014, 266,202 shares remained available for issuance under the plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan (2010 Purchase Plan), which became effective on November 10, 2011, 214,285 shares of common stock were reserved for future issuance. On May 9, 2013 an additional 185,715 shares of common stock were added to the shares reserved for future issuance under the 2010 Purchase Plan. As of March 31, 2014, 296,808 shares remained available for issuance under the plan.

Share-based Compensation

Share-based compensation expense for the three months ended March 31, 2014 and 2013, and from inception through March 31, 2014 was $2.1 million, $966,000, and $15.0 million, respectively, and is allocated between research and development and general and administrative expenses within the consolidated statements of operations, giving rise to a related tax benefit of $0 for all periods.

As of March 31, 2014, the total compensation cost related to nonvested option awards not yet recognized was $13.7 million and the weighted average period over which it is expected to be recognized is 3.2 years.

The following table summarizes the stock option activity for the three months ended March 31, 2014:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	4,486,564	$5.89	
Options granted	551,900	23.42	
Options exercised	(240,643)	5.14	
Options forfeited	(7,821)	13.57	
Options expired	—	—	
Outstanding at end of period	4,790,000	$7.94	7.0
Options exercisable at end of period	3,248,331	$4.44	6.0

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The following table summarizes options that were granted during the three months ended March 31, 2014, and the range of assumptions used to estimate the fair value of those stock options using a Black-Scholes valuation model:

Risk-free interest rate	1.96%-2.24%
Expected dividend yield	—%
Expected volatility	57.4%-60.3%
Expected term (in years)	6.9-7.0
Weighted average grant-date fair value per share	$13.75

The intrinsic value of options exercised during the three months ended March 31, 2014 was $6.5 million. The fair value of awards vested during the three months ended March 31, 2014 was $2.1 million.

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 so long as such common stock remains subject to any such restrictions. A holder of restricted stock has all rights of a shareholder 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 equity classified 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 Company's Common Stock on the The NASDAQ Stock Market on the date of grant.

During the three months ended March 31, 2014 and 2013, respectively, there were 118,700 and 0 shares of restricted stock granted. These restricted stock grants had a weighted average fair value (per share) at date of grant of $21.77. At March 31, 2014 and December 31, 2013, there were 78,700 and 0 shares of unvested restricted stock outstanding, respectively. Compensation expense is determined 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.

A summary of the Company’s unvested restricted stock at March 31, 2014 and changes during the three months ended March 31, 2014 is as follows:

	Restricted Stock	Weighed Average Grant Date Fair Value
Unvested at December 31, 2013	—	$—
Granted	118,700	21.77
Vested	(40,000)	21.38
Forfeited/cancelled	—	—
Unvested restricted stock at March 31, 2014	78,700	$21.96

As of March 31, 2014, the total remaining unrecognized compensation cost related to issuances of restricted stock was approximately $1.6 million, and is expected to be recognized over a weighted-average period of 3.8 years.

5. Income Taxes

The company incurred no income tax expense for the three months ended March 31, 2014 and 2013 and $130,000 since inception. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

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The valuation allowance for deferred tax assets as of March 31, 2014 and December 31, 2013 was $26.9 million and $25.2 million, respectively. The net change in the total valuation allowance for the three months ended March 31, 2014 and 2013 was an increase of $1.8 million and $2.7 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 March 31, 2014 and December 31, 2013, due to the uncertainty of future recoverability.
Based on analysis from inception through December 31, 2011, we believe that NewLink 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 limit NewLink'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, 2011 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 our 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.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2011 and/or changes in our ownership that resulted from our follow-on offering or our ATM Offering have caused or will cause another ownership change to occur. Any such change could result in significant limitations on some or all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred, 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.

6. Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their 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 March 31,	
	2014	2013
Historical net loss per share		
Numerator		
Net loss attributable to common stockholders	$(9,236)	$(7,934)
Denominator		

Weighted-average common shares outstanding (basic and diluted)	27,605,910	23,860,469
Basic and diluted net loss per share	$(0.33)	$(0.33)

As of March 31, 2014 and 2013 respectively, 4.8 million and 4.4 million common equivalent shares of potentially dilutive securities were not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive.

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7. Commitments and Contingencies

As of March 31, 2014, there were no significant changes in outstanding commitments or contingencies as disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and such statements are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information available to our management as of the date hereof. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "po expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: our 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 trial for our algenpantucel-L cancer immunotherapy; the timing of release of data from ongoing clinical studies; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the clinical utility of our product candidates; our plans to leverage our existing technologies to discover and develop additional product candidates; our ability to quickly and efficiently identify and develop product candidates; our 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, 2013. 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 immunotherapy product candidates intended to treat a wide range of oncology indications. Our product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. We have two proprietary cancer immunotherapy technology platforms that independently stimulate immune activation and disrupt tumor-mediated immunosuppression; HyperAcute vaccines which induce immune activation and IDO (Indoleamine 2.3-dioxygenase) pathway inhibitors which block immunosuppression.

Our lead HyperAcute product candidate, algenpantucel-L (HyperAcute Pancreas) is being studied in two randomized Phase 3 clinical trials. The first trial, IMPRESS (Immunotherapy for Pancreatic Resectible Cancer Survival Study) has completed enrollment of 722 patients with resected pancreas cancer and is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA. A second Phase 3 Trial, PILLAR (Pancreatic Immunotherapy with algenpantucel-L for Locally Advanced non-Resectible disease), is currently enrolling patients. We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free

and overall survival. We have received Fast Track and Orphan Drug designations from the FDA for algenpantucel-L for the adjuvant treatment of patients with surgically-resected pancreatic cancer and Orphan Medicinal Product designation for algenpantucel-L from the European Commission. The primary endpoint for our IMPRESS trial with algenpantucel-L for patients with surgically-resected pancreatic cancer is overall survival and, as determined by the SPA, the first interim analysis was conducted when 222 deaths were reported for the study, which occurred during the quarter ending March 31, 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 their review, the DSMC recommended that the study should proceed as planned, without modification. A second interim analysis is planned upon reaching 333 patient events and, if needed, a final analysis is planned at 444 patient events. Our additional Hyper Acute product candidates in clinical development include tergenpumatucel-L (HyperAcute Lung), dorgenmeltucel-L (HyperAcute Melanoma), HyperAcute Prostate and Hyper Acute Renal. To date, our HyperAcute product candidates have been dosed in more than 500 cancer patients, either as a monotherapy or in combination with other treatments and have demonstrated a favorable safety profile.

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Our HyperAcute immunotherapy platform creates novel biologic products that are designed to stimulate the human immune system to recognize and attack cancer cells. HyperAcute product candidates are composed of human cancer cells that are tumor specific, but not patient specific. These cells have been modified to express alpha-gal, a carbohydrate for which humans have pre-existing immunity. These alpha-gal-modified cells stimulate a rapid and powerful human immune response that trains the body's natural defenses to seek out and destroy cancer cells. The objective of HyperAcute immunotherapies is to elicit an antitumor response by "educating" the immune system to attack a patient's own cancer cells. HyperAcute 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 HyperAcute products result in the stimulation of a robust immune response.

In addition to our HyperAcute platform, we have an active drug discovery and clinical development program focused on the IDO (indoleamine-(2,3)-dioxygenase) pathway. Our IDO pathway inhibitors represent a key class of immune checkpoint inhibitors that are regarded as potential breakthrough approaches to cancer therapy. We currently have two distinct IDO pathway inhibitor product candidates in clinical development, indoximod and NLG919, with different and potentially complementary mechanisms of action. Additionally, we are conducting ongoing drug discovery work to explore new chemical entities, which inhibit IDO as well as a related target, TDO (tryptophan-2,3 dioxgynase), as potential new anticancer agents . Our most advanced IDO pathway inhibitor, indoximod, is in multiple Phase 1 and 2 clinical trials for the treatment of patients with breast, prostate, pancreas, and brain cancers. Additionally, NLG919 is currently in Phase 1 clinical development for patients with recurrent advanced solid tumors. We have generated encouraging preclinical data that demonstrate the potential of combining multiple immunotherapies including multiple checkpoint inhibitors that target the IDO pathway for enhanced anti-tumor activity.
Our small molecule IDO pathway inhibitor drug candidates are designed to counteract immunosuppressive effects of the IDO pathway, a fundamental mechanism regulating immune response. In many different cancers, IDO can be overexpressed directly either on cancer cells or by antigen presenting cells in the tumor microenvironment, representing a substantial drug development opportunity. When IDO is expressed by developing cancers, IDO pathway activity creates an immunosuppressive environment that shifts the immune response from anti-cancer to cancer tolerance. Multiple elements of the immune system are affected by this shift, including T-cells, regulatory T-cells, and dendritic cells, resulting in the survival of malignant cells that might otherwise be recognized and attacked by the immune system. Inhibiting the IDO pathway reprograms the immune response from tolerance back to an active anti-cancer response.

BioProtection Systems Corporation, or BPS, was founded by us as a subsidiary in 2005 to research, develop and commercialize 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. BPS is based on three core technologies, each of which can be leveraged into the infectious disease or biodefense fields. The first is our HyperAcute immunotherapy technology, which is currently focused on enhancing vaccines for influenza. The second technology is based on a yellow fever virus. The third technology is a replication competent recombinant Vesicular Stomatitis Vaccine, or rVSV, an advanced vaccine technology developed for the Marburg and Ebola viruses.

We are a development stage company and have incurred significant losses since our inception. As of March 31, 2014, we had an accumulated deficit of $145.2 million. We incurred net losses of $9.2 million, $7.9 million, and $145.2 million, for the three months ended March 31, 2014 and 2013, and since inception, 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 begin to build 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.

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Financial Overview

Revenues

From our inception through March 31, 2014, we have not generated any revenue from product sales. We have generated $8.8 million in grant revenue from our inception through March 31, 2014, which is primarily attributable to research and development being performed by our subsidiary, BPS, under contracts and grants with the Department of Defense, or DOD, and the National Institutes of Health, or NIH.

In the future, we may generate revenue from a variety of sources, including product sales (if we develop products that are approved for sale), license fees, and milestone, research and development and royalty payments in connection with strategic collaborations or licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research and development reimbursements, milestone and other payments we may receive under potential strategic collaborations, and the amount and timing of payments we may receive upon the sale of any products, if approved, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or to obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of:

- employee-related expenses, which include salaries, bonuses, benefits and share-based compensation;
- the cost of acquiring and manufacturing clinical trial materials;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- facilities, depreciation of fixed assets and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment related to research and development;
- license fees for and milestone payments related to in-licensed products and technology; and
- costs associated with non-clinical activities and regulatory approvals.

We expense research and development expenses as incurred.

Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size, duration and complexity of later stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we seek to complete development of our most advanced product candidates, and to further advance our earlier-stage research and development projects. From our inception through March 31, 2014, we have incurred $107.3 million in research and development expenses. The following tables summarize our research and development expenses for the periods indicated:

Research and Development Expenses by Product
(In thousands)
(unaudited)

	Three Months Ended March 31,	Cumulative from June 4, 1999 (inception)

	2014	2013	through March 31, 2014
HyperAcute immunotherapy technology	$4,681	$3,833	$76,024
IDO pathway inhibitor technology	1,196	2,085	21,046
Other research and development	510	425	10,186
Total research and development expenses	$6,387	$6,343	$107,256

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Research and Development Expenses by Category
(In thousands)
(unaudited)

	Three Months Ended March 31,		Cumulative from June 4, 1999 (inception) through March 31,
	2014	2013	2014
Compensation	$3,247	$2,340	$50,534
Equipment, supplies and occupancy	1,446	1,329	31,824
Outside clinical and other	1,694	2,674	24,898
Total research and development expenses	$6,387	$6,343	$107,256

At this time, we cannot accurately estimate or know the nature, specific timing or costs necessary to complete clinical development activities for our product candidates. We are subject to the numerous risks and uncertainties associated with developing biopharmaceutical products including the uncertain cost and outcome of ongoing and planned clinical trials, the possibility that the FDA or another regulatory authority may require us to conduct clinical or non-clinical testing in addition to trials that we have planned, rapid and significant technological changes, frequent new product and service introductions and enhancements, evolving industry standards in the life sciences industry and our future need for additional capital. In addition, we currently have limited clinical data concerning the safety and efficacy of our product candidates. A change in the outcome of any of these variables with respect to the development of any of our product candidates could result in a significant change in the costs and timing of our research and development expenses.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise associated with research and development expenses, intellectual property prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will continue to increase over the next several years for, among others, the following reasons:

- we expect our general and administrative expenses to increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, auditing and tax services and investor relations costs, and director and officer insurance premiums associated with being a public company;
- we expect to incur increased general and administrative expenses to support our research and development activities, which we expect to expand as we continue to advance the clinical development of our product candidates; and
- we expect to incur increased expenses related to the planned sales and marketing of our product candidates, which may include recruiting a specialty sales force, in anticipation of commercial launch before we receive regulatory approval, if any, of a product candidate.

Interest Income and Interest Expense

Interest income consists of interest earned on our cash and cash equivalents and certificates of deposit. The primary objective of our investment policy is capital preservation. We expect our interest income to increase as we invest the net proceeds from our offerings pending their use in our operations.

Interest expense consists primarily of interest and amortization of deferred financing costs associated with our notes payable and obligations under capital leases.

Tax Loss Carryforwards

The valuation allowance for deferred tax assets as of March 31, 2014 and December 31, 2013 was $26.9 million and $25.2 million, respectively. The net change in the total valuation allowance for the three months ended March 31, 2014 and

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2013 was an increase of $1.8 million and $2.7 million, respectively. In assessing the realizability of deferred tax assets, we consider 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. We consider the scheduled reversal of deferred tax liabilities, projected taxable income, and tax planning strategies in making this assessment. Valuation allowances have been established for the entire amount of the net deferred tax assets as of March 31, 2014 and December 31, 2013, due to the uncertainty of future recoverability.

As of March 31, 2014 and December 31, 2013, we had federal net operating loss carryforwards of $96.1 million and $88.4 million and federal research credit carryforwards of $4.3 million and $4.3 million, respectively, that expire at various dates from 2019 through 2033. 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, 2011, we believe that 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 limit our ability to utilize federal net operating loss carryforwards (and certain other tax attributes) that accrued prior to our ownership changes and those of BPS.

Additional analysis will be required to determine whether changes in our ownership since December 31, 2011 and/or changes in our ownership that resulted from our follow-on offering or our ATM Offering have caused or will cause another ownership change to occur. Any such change could result in significant limitations on some or all of our net operating loss carryforwards and other tax attributes.

Even if another ownership change has not occurred, 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.

Income tax expense was $0 for the three months ended March 31, 2014 and 2013. Income tax expense differs from the amount that would be expected after applying the statutory U.S. federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our financial statements in accordance with United States generally accepted accounting principles. Our preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements, as well as revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions. We have reviewed our critical accounting policies and estimates

with the Audit Committee of our Board of Directors.

Our Annual Report on Form 10-K for the year ended December 31, 2013, discusses our most critical accounting policies. Since December 31, 2013, there have been no material changes in the critical accounting policies discussed in the 2013 Annual Report.

Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2013

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Revenues. Revenues for the three months ended March 31, 2014 were $334,000, increasing from $302,000 for the same period in 2013. The increase in revenue of $32,000 was due to an increase in billings by BPS under various DOD contracts and NIH grants.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2014 were $6.4 million, increasing from $6.3 million for the same period in 2013. The $44,000 increase was due to an increase of $908,000 in personnel-related expenses, accompanied by a $44,000 increase in equipment and supplies, and offset by a $906,000 decrease in contract research and manufacturing and consulting fees. The decrease in contract research and manufacturing and consulting fees is primarily attributable to the completion of certain contract research services agreements, and the increase in personnel-related expense is attributable to both increases in headcount and compensation levels, including share-based compensation.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2014 were $3.3 million, increasing from $2.0 million for the same period in 2013. The $1.3 million increase was primarily due to an increase of $648,000 in share-based compensation expense, accompanied by an increase of $437,000 in wages, an increase of $140,000 in travel and other expenses, and an increase of $122,000 in legal and consulting fees.

Net Loss. Net loss for the three months ended March 31, 2014 was $9.2 million, increasing from $7.9 million for the same period in 2013 due to the changes in research and development and general and administrative expenses discussed above. The weighted average common shares outstanding for the first quarter 2014 were 27.6 million, resulting in a loss per share of $(0.33), as compared to 23.9 million and $(0.33) per share for first quarter 2013. The increase in the number of weighted average common shares outstanding was primarily attributable to shares issued in our follow-on public offering in February 2013, and our ATM Offering during the fourth quarter of 2013 and the first quarter of 2014.

Liquidity and Capital Resources

Before our IPO, we funded our operations principally through the private placement of equity securities, debt financing and interest income. As of March 31, 2014, we have received proceeds, net of offering costs, of $209.7 million from the issuance of common and convertible preferred stock, and from debt financing. This includes $7.5 million from the sale of 1.5 million shares of Series D preferred stock in July 2009, $30.0 million from the sale of 6.0 million shares of Series C preferred stock during the course of 2008 and 2009, and $21.4 million from the sale of 684,624 shares of Series E preferred stock during the course of 2010 and the first half of 2011, of which $8.6 million was issued to acquire the minority interest in BPS.

Since our IPO, we have funded our operations principally through public offerings of common stock. On November 16, 2011, we received proceeds, net of offering costs, of $37.6 million from the issuance of 6.2 million shares of common stock in our IPO. On February 4, 2013, we received proceeds, net of offering costs, of $49.0 million from the issuance of 4.6 million shares of common stock in our follow-on offering. As of March 31, 2014, we had sold 1.8 million shares of common stock in our ATM Offering, raising a total of $45.0 million in net proceeds. Subsequent to March 31, 2014, we sold no additional shares of common stock under the ATM Offering raising no additional net proceeds.

As of March 31, 2014, we had cash, cash equivalents and certificates of deposit of approximately $84.0 million. 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

(in thousands)

	Three Months Ended March 31,	
	2014	2013
Net cash used in development activities	$(6,067)	$(6,623)
Net cash (used in) provided by investing activities	(93)	685
Net cash provided by financing activities	28,582	48,966
Net increase in cash and cash equivalents	$22,422	$43,028

For the three months ended March 31, 2014 and 2013, we used cash of $6.1 million and $6.6 million for our development activities, respectively. The cash used by development activities in the three months ended March 31, 2014 primarily resulted from our net loss of $9.2 million, offset by non-cash expenses of $2.4 million (primarily share-based compensation and

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depreciation) and offset by changes in operating assets and liabilities of $808,000. The cash used by development activities in the three months ended March 31, 2013 primarily resulted from our net loss of $7.9 million, offset by non-cash expenses of $1.2 million, accompanied by changes in operating assets and liabilities of $133,000.

For the three months ended March 31, 2014 and 2013, our investing activities used cash of $93,000 and provided cash of $685,000, respectively. The cash used by investing activities in the three months ended March 31, 2014 was a result of the purchase of fixed assets of $93,000. The cash provided by investing activities in the three months ended March 31, 2013 was primarily a result of the sale of investments of $747,000, offset by the purchase of equipment of $62,000.

For the three months ended March 31, 2014 and 2013, our financing activities provided $28.6 million and $49.0 million, respectively. The cash provided by financing activities in the three months ended March 31, 2014 was primarily due to the sale and issuance of common stock of $27.6 million, accompanied by the exercise of stock options of $1.2 million, offset by the repurchase of common stock of $182,000. The cash provided by financing activities in the three months ended March 31, 2013 was primarily due to the sale and issuance of common stock of $49.0 million.

As previously disclosed, we entered into a Sales Agreement, by and between us and Cantor Fitzgerald & Co., dated as of September 5, 2013, or the Cantor Agreement, pursuant to which we may issue and sell up to $60.0 million in shares of our common stock in one or more placements at prevailing market prices for our common stock. Any such sales would be effected pursuant to our registration statement on Form S-3 (333-185721), declared effective by the SEC on January 4, 2013. As of March 31, 2014, the Company had sold 1.8 million shares of common stock under the ATM Offering, raising a total of $45.0 million in net proceeds. Subsequent to March 31, 2014, the Company sold no additional shares of common stock under the ATM Offering.

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses in the future as we incur expenses related to the research and development of our HyperAcute immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure. Including the funds received from our follow-on public offering in February 2013 and the funds received to date from our ATM Offering, we believe that we have sufficient cash and cash equivalents and certificates of deposit to fund our operations well into 2015, although not through commercialization and launch of revenue producing products.

We may seek to sell additional equity securities, which may include anticipated sales of our common stock pursuant to the Cantor Agreement, if any, or otherwise, or debt securities or to 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 shareholders. 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 are 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 estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

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

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Contractual Obligations and Commitments

There are no material changes to our contractual obligations as disclosed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 12, 2014.

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Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of March 31, 2014 and December 31, 2013, we had cash and cash equivalents and certificates of deposit of $84.0 million and $61.5 million, respectively, consisting of money market funds and 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 short-term marketable securities. 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 March 31, 2014. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of March 31, 2014, 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

We implemented a new enterprise resource planning, or ERP, system in the third quarter of 2013. As of March 31, 2014, the ERP system was used for certain manufacturing and finance purposes and we expect the ERP system to be used for other manufacturing and finance functions in 2014. The new ERP system did not eliminate any existing controls over financial reporting. In addition, the ERP system can support internal controls over some items that our previous accounting system did not support.

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

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PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. 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 resected pancreatic cancer. If we fail to complete, or fail to demonstrate safety and efficacy in, 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 products. Our most advanced 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 no significant safety issues and whether the FDA agrees that the data from either of our Phase 3 clinical trials of algenpantucel-L are sufficient to support approval. 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 study who do not receive algenpantucel-L may not have results similar to patients studied in the other studies we have

used for comparison to our Phase 2 studies. If the patients in our Phase 3 study who receive standard-of-care without algenpantucel-L have results which are better than the results predicted by the other large studies, we may not demonstrate a sufficient benefit from algenpantucel-L to allow or convince the FDA to approve it for marketing.

Our HyperAcute 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 product candidates are based on our novel HyperAcute 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 larger-scale production. If we make any changes to our current manufacturing methods or cannot design assays that satisfy the FDA's expectations regarding the equivalency of such therapeutics in the laboratory, 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 Special Protocol Assessment, or SPA, with the FDA relating to our algenpantucel-L IMPRESS (Immunotherapy for Pancreatic Resectable Cancer Survival Study) 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 study design, including trial size, clinical endpoints and/or data analyses are acceptable to the FDA. However, the SPA agreement is not a guarantee of approval. 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 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. Although the SPA agreement calls for review of interim data at certain times prior to completion, there is no assurance that any such review, even if such interim data are positive, will result in early approval. 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, or whether algenpantucel-L will receive any regulatory approvals as a result of the SPA agreement or the IMPRESS Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for algenpantucel-L for the treatment of patients with 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 INDs to lapse into inactive status, and we

may in the future decide to forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater scientific or commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. Furthermore, our resource allocation decisions, and our decisions about whether and how to develop or commercialize any particular product candidate may be based on evaluations of the scientific and commercial potential or target market for the product candidate that later prove to be materially inaccurate. If we enter into collaborations, licensing or other royalty arrangements to develop or commercialize a particular product candidate, we may relinquish valuable rights to that product candidate in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

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

We have not completed all 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 study 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 study 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 the HyperAcute product candidates, indoximod, or other IDO pathway inhibitor product candidates such as NLG919, prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize the HyperAcute product candidates, indoximod, NLG919 or other future 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. We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, 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;
- the size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;

- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

In particular, 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. In addition, 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.

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. 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.

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.

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 current Good Clinical Practices, or cGCP, 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 Practices, or cGMP, and may require large numbers of test subjects. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

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deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;

- deficiencies in the clinical trial operations or trial sites;
- 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;
- the product candidate may not appear to be more effective than current therapies;
- 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 product candidates, indoximod, NLG919 and other product candidates could take a significantly longer time to gain regulatory approval for any additional indications than we expect or we may never gain approval for additional indications, which could reduce our revenue by delaying or terminating the commercialization of our HyperAcute product candidates, indoximod, NLG919 and other product candidates for additional indications.

Some of our product candidates have been or in the future may be studied in clinical trials co-sponsored by the National Cancer Institute, or NCI, or in investigator-initiated clinical trials, which means we have little control over the conduct of such trials.

Our indoximod product candidate has been studied in two Phase 1B/2 clinical trials co-sponsored by the National Cancer Institute. We are currently supplying our indoximod product candidate in support of a Phase 2 investigator-initiated clinical trial, and we provided clinical supply of our dorgenmeltucel-L (HyperAcute Melanoma) product candidate in support of a Phase 2 investigator-initiated clinical trial. 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 have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing will be successful. We may experience numerous unforeseen events during, or as a result of, the preclinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

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

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

Even if approved, the HyperAcute product candidates, indoximod, NLG919 or any other product we may commercialize and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our products. We 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 that may be expensive and/or time consuming to fulfill. In

addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our 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 of 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, and seek FDA approval for our production process simultaneously with seeking approval for the marketing and sale of our algenpantucel-L. Should we not receive timely approval of our production process, our ability to produce the immunotherapy 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 any products that we develop ourselves.

We may establish our own specialty sales force and/or engage other biopharmaceutical or other healthcare companies with established sales, marketing and distribution capabilities to sell, market and distribute any future products. We may not be able to establish a specialty sales force or establish sales, marketing or distribution relationships on acceptable terms. Factors that may inhibit our efforts to commercialize any future products without strategic collaborators or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to 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 either of their services might significantly delay or prevent the achievement of our research, development, and business objectives. We do not maintain key-man life insurance with respect to any of our employees, nor do we intend to secure such insurance.

We will need to recruit 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 that have contingently agreed to join us do not join us it will be difficult or impossible for us to execute our business plan in a timely manner. Additionally, our 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. We may develop our manufacturing capacity by expanding our current facilities, by entering into 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 third-party commercial manufacturing would require expertise and qualified personnel to manage such relationships and may 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 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 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 existing contract manufacturer for indoximod and the components used in the HyperAcute product candidates, our contract manufacturer for NLG919, one of our IDO pathway inhibitor candidates, and any contract manufacturer that we may use in the future for manufacturing related to clinical trials or commercial sale 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. 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 the HyperAcute product candidates, indoximod, NLG919 or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of the HyperAcute product

candidates, indoximod, NLG919 or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third party contractors. 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 NLG919, we are or will be subject to additional risks including the need to comply with export and import regulations.

We currently rely on relationships with third-party contract manufacturers, which limits our ability to control the availability of, and manufacturing costs for, our product candidates in the near-term.

We intend to rely upon contract manufacturers for indoximod, NLG919, and for components of or finished HyperAcute product candidates, for commercial sale if any are approved for sale. In addition, we currently rely on a contract manufacturer for supply of NLG919 for preclinical and clinical studies. Problems with any of our facilities or processes, or our contract manufacturers' facilities or processes, could prevent or delay the production of adequate supplies of antigen, components of or finished HyperAcute product candidates, indoximod or NLG919. 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 regulatory requirements or standards that require modifications to our manufacturing processes, action by the 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 timely meet market demand for any products that are approved for sale.

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 our products internally and utilize a single manufacturing site to manufacture our clinical product candidates. Any disruption in the operations of our manufacturing facility would have a significant negative impact on our ability to manufacture products for clinical testing and would result in increased costs and losses.

We have thus far elected to replicate all biological cells for our products 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 clinical products. 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 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 manufacturing facility would have a significant negative impact on our ability to manufacture products 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 ou