NEWLINK GENETICS CORP
Form 10-Q
August 08, 2013
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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 June 30, 2013.
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 August 5, 2013, there were 25,701,354 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

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PART I

NewLink Genetics Corporation
(A Development Stage Enterprise)

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

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$59,039	$20,250
Certificates of deposit	249	1,494
Prepaid expenses	535	907
State research and development credit receivable	436	542
Other receivables	812	196
Total current assets	61,071	23,389
Leasehold improvements and equipment:		
Leasehold improvements	5,249	5,085
Computer equipment	668	636
Lab equipment	3,428	3,297
Total leasehold improvements and equipment	9,345	9,018
Less accumulated depreciation and amortization	(3,403)	(2,978)
Leasehold improvements and equipment, net	5,942	6,040
Total assets	$67,013	$29,429

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
(A Development Stage Enterprise)

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

	June 30, 2013	December 31, 2012
Liabilities and Equity		
Current liabilities:		
Accounts payable	$1,076	$972
Accrued expenses	2,817	1,659
Deferred rent	84	84
Obligations under capital lease and current portion of notes payable	186	204
Total current liabilities	4,163	2,919
Long term liabilities:		
Royalty obligation payable to Iowa Economic Development Authority	6,000	6,000
Notes payable and obligations under capital leases	1,129	1,178
Deferred rent, excluding current portion	1,363	1,405
Total long-term liabilities	8,492	8,583
Total liabilities	12,655	11,502
Commitments and contingencies		
Equity:		
Blank check preferred stock, $0.01 par value: Authorized shares — 5,000,000 at June 30, 2013 and December 31, 2012; issued and outstanding shares — 0 at June 30, 2013 and December 31, 2012	—	—
Common stock, $0.01 par value: Authorized shares — 75,000,000 at June 30, 2013 and 38,833,334 at December 31, 2012; issued and outstanding shares — 25,700,286 at June 30, 2013, and 20,985,192 at December 31, 2012	257	210
Additional paid-in capital	173,909	122,514
Deficit accumulated during the development stage	(119,808)	(104,797)
Total equity	54,358	17,927
Total liabilities and equity	$67,013	$29,429

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
(A Development Stage Enterprise)

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

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30,
	2013	2012	2013	2012	2013
Grant revenue	$232	$590	534	1,061	$ 7,938
Operating expenses:					
Research and development	5,037	4,740	11,380	8,570	89,536
General and administrative	2,264	2,151	4,265	3,609	41,208
Total operating expenses	7,301	6,891	15,645	12,179	130,744
Loss from operations	(7,069)	(6,301)	(15,111)	(11,118)	(122,806)
Other income and expense:					
Miscellaneous income (expense)	—	—	114	(21)	434
Forgiveness of debt	—	—	—	—	449
Interest income	2	4	4	8	1,771
Interest expense	(10)	(12)	(18)	(20)	(199)
Other income (expense), net	(8)	(8)	100	(33)	2,455
Net loss	(7,077)	(6,309)	(15,011)	(11,151)	(120,351)
Less net loss attributable to noncontrolling interest	—	—	—	—	583
Net loss attributable to NewLink	$(7,077)	$(6,309)	(15,011)	(11,151)	$ (119,768)
Net loss per common share, basic and diluted	$(0.28)	$(0.31)	$(0.61)	$(0.54)	
Weighted-average common shares outstanding, basic and diluted	25,620,566	20,684,944	24,745,380	20,649,045	

See accompanying notes to condensed consolidated financial statements.

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NewLink Genetics Corporation
(A Development Stage Enterprise)
Condensed Consolidated Statements of Equity (Deficit)
(unaudited)
(In thousands, except share and per share data)

	Common Stock				
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Equity (Deficit)
Balance at December 31, 2012	20,985,192	$210	$122,514	$ (104,797)	$17,927
Stock compensation	—	—	2,027	—	2,027
Exercise of stock options	86,867	1	322	—	323
Sale of shares under stock purchase plan	28,227	—	176	—	176
Issuance of 4,600,000 shares of common stock (net of offering costs of $3,524) (February 4, 2013)	4,600,000	46	48,870	—	48,916
Net loss	—	—	—	(15,011)	(15,011)
Balance at June 30, 2013	25,700,286	$257	$173,909	$ (119,808)	$54,358

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30,
	2013	2012	2013
Cash Flows From Development Activities			
Net loss	$(15,011)	$(11,151)	$(120,351)
Adjustments to reconcile net loss to net cash used in development activities:			
Share-based compensation	2,027	1,905	10,571
Depreciation and amortization	425	372	4,174
Loss on sale of fixed assets	—	20	38
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	372	155	(535)
State research and development credit receivable	107	(130)	(435)
Other receivables	(617)	(1,015)	(813)
Accounts payable	104	(1,095)	(156)
Accrued expenses and deferred rent	1,116	490	4,264
Net cash used in development activities	(11,477)	(10,449)	(101,713)
Cash Flows From Investing Activities			
Purchase of certificates of deposit	—	—	(13,282)
Sale of certificates of deposit	1,245	1,743	13,033
Notes receivable from related parties	—	—	(350)
Purchase of equipment	(274)	(1,114)	(8,366)
Proceeds on sale of equipment	—	50	50
Cash paid for OncoRx	—	—	(120)
Net cash provided by (used in) investing activities	971	679	(9,035)
Cash Flows From Financing Activities			
Cash received from noncontrolling interest investment	—	—	3,479
Issuance of common stock, net of offering costs	49,416	709	91,861
Repurchase of common stock	—	(4)	(505)
Proceeds from preferred stock	—	—	67,743
Proceeds from notes payable	—	—	8,215
Principal payments on debt	(74)	(47)	(550)
Payments under capital lease obligations	(47)	(51)	(456)
Net cash provided by financing activities	49,295	607	169,787
Net increase (decrease) in cash and cash equivalents	38,789	(9,163)	59,039
Cash and cash equivalents at beginning of period	20,250	39,490	—
Cash and cash equivalents at end of period	$59,039	$30,327	$59,039
Supplemental disclosure of cash flows information:			

Cash paid for interest	$18	$20	$150
Noncash financing and investing activities:			
Accretion on redeemable preferred stock	—	—	113
Purchased leasehold improvements and equipment in accounts payable	71	22	9
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 Subsidiary
(A Development Stage Enterprise)
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Business and Development Stage Activities

NewLink Genetics Corporation ("NewLink") is a biopharmaceutical company focused on discovering, developing and commercializing novel immunotherapeutic products to improve treatment options for patients with cancer. NewLink was incorporated as a Delaware corporation on June 4, 1999 and initiated operations in April of 2000. In 2005, NewLink created a wholly-owned subsidiary, BioProtection Systems Corporation (BPS). NewLink and BPS (together referred to herein as the "Company") are development stage enterprises that devote substantially all of their efforts toward research and development.

NewLink's portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink's 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.

The Company has never earned revenue from sales of its drugs under development. The Company incurred net losses of $7.1 million and $15.0 million for the three and six months ended June 30, 2013, and from June 4, 1999 (inception) through June 30, 2013 has generated a cumulative deficit of $119.8 million. On November 16, 2011, the Company completed its initial public offering (IPO) of common stock raising $37.6 million in net proceeds. On February 4, 2013, the Company completed a follow-on offering of its common stock raising $48.9 million in net proceeds.

The accompanying financial statements as of June 30, 2013 and for the three and six months then ended have been prepared assuming the Company will continue as a going concern. Our cash and cash equivalents are expected to be adequate to satisfy the Company’s liquidity requirements through December 31, 2014, although not through commercialization and launch of revenue producing products. 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.

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, 2012, 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 2012. 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 BPS. 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, accounts payable, and accrued liabilities, 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 $1.3 million and $1.4 million as of June 30, 2013 and

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December 31, 2012, respectively, and was determined using Level 3 inputs. The Company is unable to estimate the fair value of the royalty obligation because the timing 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.

(d) Corporate Actions During the Quarter Ended June 30, 2013

On May 9, 2013, the stockholders of the Company approved the following actions:

- An increase in the authorized number of shares of common stock from 38,833,334 shares to 75,000,000 shares;
- An increase in the shares reserved under the 2010 Non-Employee Directors' Stock Award Plan of 161,905 shares from 238,095 shares to 400,000 shares of common stock; and
- An increase in the shares reserved under the 2010 Employee Stock Purchase Plan of 185,715 shares from 214,285 shares to 400,000 shares of common stock.

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. On January 1, 2013 an additional 838,375 shares of common stock were added to the shares reserved for future issuance under the Company's 2009 Equity Incentive Plan. The shares added to the reserve on January 1, 2013 were increased 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 of Common Stock outstanding on December 31 of the preceding calendar year. As of June 30, 2013, there were 5,733,514 shares of common stock authorized for the 2009 plan and 702,409 shares remained available for issuance.

Under the terms of the Company's 2010 Non-Employee Directors' Stock Option Plan, or 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 June 30, 2013, 266,202 shares remained available for issuance under the plan.

Under the terms of the Company's 2010 Employee Stock Purchase Plan, or 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 June 30, 2013, 332,250 shares remained available for issuance under the plan.

Stock Options

Share-based employee compensation expense for the three and six months ended June 30, 2013, the three and six months ended June 30, 2012, and from inception through June 30, 2013 was $1.1 million, $2.0 million, $1.2 million, $1.9 million, and $10.6 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 June 30, 2013, the total compensation cost related to nonvested option awards not yet recognized was $8.6 million and the weighted average period over which it is expected to be recognized is 2.9 years.

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The following table summarizes the stock option activity for the six months ended June 30, 2013:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)
Outstanding at beginning of period	3,752,413	$4.34	
Options granted	815,250	12.25	
Options exercised	(86,867)	3.71	
Options forfeited	(4,619)	11.46	
Options expired	—	—	
Outstanding at end of period	4,476,177	$5.78	7.3
Options exercisable at end of period	2,859,887	$3.62	6.4

Based on the June 28, 2013 closing price of $19.72 per share, the intrinsic value of stock options outstanding as of June 30, 2013, was $62.4 million, of which $46.1 million and $16.3 million related to stock options that were vested and unvested, respectively, at that date.

The following table summarizes options that were granted during the six months ended June 30, 2013, 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	1.12%-1.36%
Expected dividend yield	—
Expected volatility	65.3%-67.3%
Expected term (in years)	6.8-7.0
Weighted average grant-date fair value per share	$7.31

The intrinsic value of options exercised during the six months ended June 30, 2013 was $1.2 million. The fair value of awards vested during the six months ended June 30, 2013 was $1.5 million.

5. Income Taxes

The company incurred no income tax expense for the six months ended June 30, 2013 and 2012 or 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.

The valuation allowance for deferred tax assets as of June 30, 2013 and December 31, 2012 was $27.3 million and $23.1 million, respectively. The net change in the total valuation allowance for the six months ended June 30, 2013 and 2012 was an increase of $4.2 million and $2.3 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 June 30, 2013 and December 31, 2012, due to the uncertainty of future recoverability.

Based on a preliminary analysis, we believe that, from its inception through December 31, 2011, NewLink experienced Section 382 ownership changes in September 2001 and March 2003 and our subsidiary 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 our

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subsidiary. Additional ownership changes 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.

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):

	Six Months Ended June 30,	
	2013	2012
Historical net loss per share		
Numerator		
Net loss attributable to common stockholders	$(15,011)	$(11,151)
Denominator		
Weighted-average common shares outstanding (basic and diluted)	24,745,380	20,649,045
Basic and diluted net loss per share	$(0.61)	$(0.54)

As of June 30, 2013 and 2012 respectively, 4.5 million and 3.8 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.

7. Commitments and Contingencies

On May 30, 2013, we entered into a Standard Design-Build Agreement, or the Story Agreement, with Story Construction Co. to provide temporary remodeling services with respect to approximately 11,800 square feet of existing manufacturing and quality control space at our headquarters in Ames, Iowa. Our obligations under the Story Agreement constitute a purchase obligation of approximately $1.0 million. The full amount is due upon substantial completion of the work, which the Story Agreement contemplates to be less than one year following the date of the Story Agreement. The Story Agreement does not affect our contractual lease obligations or other contractual obligations.

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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 products; 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, 2012. 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 lead product candidate, HyperAcute Pancreas cancer immunotherapy (algenpantucel-L), or HyperAcute Pancreas, is being studied in two Phase 3 clinical trials; one in surgically-resected pancreatic cancer patients that is being performed under a Special Protocol Assessment, or SPA, with the United States Food and Drug Administration, or FDA, and one in locally advanced pancreatic cancer patients. We initiated these trials based on encouraging Phase 2 data that suggest improvement in both disease-free and overall survival. We have also received Fast Track and Orphan Drug designations from the FDA for this product candidate for the adjuvant treatment of surgically-resected pancreatic cancer and Orphan Medicinal Product designation for this product candidate from the European Commission. The primary endpoint for our IMPRESS (Immunotherapy for Pancreatic Resectable cancer Survival Study) Phase 3 trial with algenpantucel-L for patients with surgically-resected pancreatic cancer is overall survival and, as determined by the SPA, the first interim analysis will be conducted when 222 deaths are reported for the study. This triggering event for the first interim analysis has not yet occurred. We have three additional product candidates in clinical development, including our HyperAcute Lung cancer immunotherapy (tergenpumatucel-L), or HyperAcute

Lung, our HyperAcute Melanoma cancer immunotherapy, or HyperAcute Melanoma and indoximod, our IDO pathway inhibitor. To date, our HyperAcute product candidates have been dosed in more than 500 cancer patients, either as a monotherapy or in combination with other therapies, and have demonstrated a favorable safety profile.

Our HyperAcute product candidates are based on our proprietary HyperAcute immunotherapy technology, which is designed to stimulate the human immune system. Our HyperAcute product candidates use allogeneic (non-patient specific) cells from previously established cell lines rather than cells derived from the patient. We believe our approach enables a simpler, more consistent and scalable manufacturing process than therapies based on patient specific tissues or cells. Our product candidates are designed to harness multiple components of the innate immune system to combat cancer, either as a monotherapy or in combination with current treatment regimens without incremental toxicity. We are also conducting small-molecule based research and development with an aim to produce new drugs capable of breaking the immune system’s tolerance to cancer through inhibition of the indoleamine-(2,3)-dioxygenase, or IDO, pathway. We are currently studying our

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lead IDO pathway inhibitor product candidate, indoximod or 1-methyl-D-tryptophan (D-1MT), in multiple Phase 2 studies in breast cancer and prostate cancer. We believe that our immunotherapeutic technologies will enable us to discover, develop and commercialize multiple product candidates that can be used either alone or in combination to enhance or potentially replace current therapies to treat cancer with underserved patient populations and significant market potential.

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 Stomatitus 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 June 30, 2013, we had an accumulated deficit of $119.8 million. We incurred net losses of $7.1 million, $15.0 million, $6.3 million, $11.2 million, and $119.8 million, for the three and six months ended June 30, 2013, the three and six months ended June 30, 2012, and since inception, respectively. We expect our losses to increase over the next several years as we advance our products 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 products receiving marketing approval.

On October 19, 2011, our board of directors approved a 2.1-for-one reverse split of our common stock which became effective upon filing of a Certificate of Amendment of the Restated Certificate of Incorporation with the Secretary of State of Delaware on October 25, 2011. All share and per share amounts have been retroactively restated in the accompanying financial statements and notes for all periods presented.

Financial Overview

Revenues

From our inception through June 30, 2013, we have not generated any revenue from product sales. We have generated $7.9 million in grant revenue from our inception through June 30, 2013, 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. We do not expect to generate revenue from product sales for several years, if ever. 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, including equipment and supplies;
- 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.

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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 June 30, 2013, we have incurred $89.5 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 June 30,		Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30,
	2013	2012	2013	2012	2013
HyperAcute immunotherapy technology	$3,877	$3,212	$7,711	$5,872	$62,812
IDO pathway inhibitor technology	835	1,066	2,920	1,861	17,997
Other research and development	325	462	749	837	8,727
Total research and development expenses	$5,037	$4,740	$11,380	$8,570	$89,536

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

	Three Months Ended June 30,		Six Months Ended June 30,		Cumulative from June 4, 1999 (inception) through June 30,
	2013	2012	2013	2012	2013
Compensation	$2,198	$2,062	$4,537	$3,971	$42,551
Equipment, supplies and occupancy	1,259	1,307	2,588	2,352	27,120
Outside clinical and other	1,580	1,371	4,255	2,247	19,865
Total research and development expenses	$5,037	$4,740	$11,380	$8,570	$89,536

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.

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

- 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;
- to support our research and development activities, which we expect to expand as we continue to advance the clinical development of our product candidates;
- as a result of beginning to incur expenses related to the planned sales and marketing of one or more of our product candidates, before we receive regulatory approval, in anticipation of commercial launch, if any, of those product candidates.

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 June 30, 2013 and December 31, 2012 was $27.3 million and $23.1 million, respectively. The net change in the total valuation allowance for the three months ended June 30, 2013 and 2012 was an increase of $4.2 million and $2.3 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 June 30, 2013 and December 31, 2012, due to the uncertainty of future recoverability.

As of June 30, 2013 and December 31, 2012, we had federal net operating loss carryforwards of $108.5 million and $94.5 million and federal research credit carryforwards of $4.1 million and $2.9 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 a preliminary analysis, we believe that, from its inception through December 31, 2011, we experienced Section 382 ownership changes in September 2001 and March 2003 and our subsidiary 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 our subsidiary. 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 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 June 30, 2013 and 2012. Income tax expense differs from the amount that would be expected after applying the statutory United States federal income tax rate primarily due to changes in the valuation allowance for deferred taxes.

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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.

Our Annual Report on Form 10-K for the year ended December 31, 2012, discusses our most critical accounting policies. Since December 31, 2012, there have been no material changes in the critical accounting policies discussed in the 2012 Annual Report.

Results of Operations

Comparison of the Three Months Ended June 30, 2013 and 2012

Revenues. Revenues for the three months ended June 30, 2013 were $232,000, decreasing from $590,000 for the same period in 2012. The decrease in revenue of $358,000 was due to decreased research by BPS under various DOD contracts and the completion of three grants in 2012.

Research and Development Expenses. Research and development expenses for the three months ended June 30, 2013 were $5.0 million, increasing from $4.7 million for the same period in 2012. The $300,000 increase was primarily due to an increase of $209,000 in clinical trial expense, accompanied by a $136,000 increase in personnel-related expenses. The increase in clinical trial expense is primarily attributable to higher levels of patient counts enrolled in our clinical trials and the increase in personnel-related expense is attributable to both increases in headcount and compensation levels.

General and Administrative Expenses. General and administrative expenses for the three months ended June 30, 2013 were $2.3 million, increasing from $2.2 million for the same period in 2012. The $100,000 increase was primarily due to an increase in consulting and dues and subscriptions, offset by decreases in recruiting and other expenses.

Interest Income and Expense. Interest expense for the three months ended June 30, 2013 was $10,000, compared to $12,000 for the same period in 2012. Interest income for the three months ended June 30, 2013 was $2,000, compared to $4,000 for the same period in 2012.

Comparison of the Six Months Ended June 30, 2013 and 2012

Revenues. Revenues for the six months ended June 30, 2013 were $534,000, decreasing from $1.1 million for the same period in 2012. The decrease in revenue of $527,000 was due to decreased research by BPS under various DOD contracts and the completion of three grants in 2012.

Research and Development Expenses. Research and development expenses for the six months ended June 30, 2013 were $11.4 million, increasing from $8.6 million for the same period in 2012. The $2.8 million increase was primarily

due to an increase in outside clinical and other expenses, including a $908,000 increase in contract research and manufacturing, an increase of $896,000 in clinical trial expense, accompanied by a $566,000 increase in personnel-related expenses, an increase of $130,000 in consulting fees and other expenses and an increase in $66,000 in maintenance and repair and other expenses. The increase in contract research and manufacturing relates primarily to small-molecule based research and development. The increase in clinical trial expense is primarily attributable to higher levels of patient counts enrolled in our clinical trials and the increase in personnel-related expense is attributable to both increases in headcount and compensation levels.

General and Administrative Expenses. General and administrative expenses for the six months ended June 30, 2013 were $4.3 million, increasing from $3.6 million for the same period in 2012. The $700,000 increase was primarily due to a $265,000 increase in personnel-related expenses, accompanied by a $346,000 increase in professional fees, travel and other expenses.

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Interest Income and Expense. Interest expense for the six months ended June 30, 2013 was $18,000, compared to $20,000 for the same period in 2012. Interest income for the six months ended June 30, 2013 was $4,000, compared to $8,000 for the same period in 2012.

Other Income (Expense). Miscellaneous income (expense), net for the six months ended June 30, 2013 was $114,000, compared to ($21,000) for the same period in 2012. Miscellaneous income (expense), net for the six months ended June 30, 2013 was primarily attributable to a rebate from our clinical trial insurance carrier.

Liquidity and Capital Resources

We have funded our operations through the proceeds of our initial public offering, or IPO, completed in November 2011, the proceeds of our follow-on public offering, completed in February 2013, the private placement of equity securities, debt financing and interest income. As of June 30, 2013, we have received proceeds of $158.0 million from the issuance of common and convertible preferred stock and $8.2 million from debt financing. As of June 30, 2013, we had cash, cash equivalents and certificates of deposit of approximately $59.3 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)

	Six Months Ended June 30,	
	2013	2012
Net cash used in development activities	$(11,477)	$(10,449)
Net cash provided by investing activities	971	679
Net cash provided by financing activities	49,295	607
Net increase (decrease) in cash and cash equivalents	$38,789	$(9,163)

For the six months ended June 30, 2013 and 2012, we used cash of $11.5 million and $10.4 million for our development activities, respectively. The cash used by development activities in the six months ended June 30, 2013 primarily resulted from our net loss of $15.0 million, offset by non-cash expenses of $2.5 million (primarily share-based compensation and depreciation) and offset by changes in operating assets and liabilities of $1.1 million. The cash used by development activities in the six months ended June 30, 2012 primarily resulted from our net loss of $11.2 million, accompanied by changes in operating assets and liabilities of $1.6 million and offset by non-cash expenses of $2.3 million.

For the six months ended June 30, 2013 and 2012, our investing activities provided cash of $971,000 and $679,000, respectively. The cash provided by investing activities in the six months ended June 30, 2013 was primarily a result of the sale of investments of $1.2 million offset by the purchase of fixed assets of $274,000. The cash provided by investing activities in the six months ended June 30, 2012 was primarily a result of the sale of investments of $1.7 million offset by the purchase of equipment of $1.1 million.

For the six months ended June 30, 2013 and 2012, our financing activities provided $49.3 million and $607,000, respectively. The cash provided by financing activities in the six months ended June 30, 2013 was primarily due to the sale and issuance of common stock of $49.4 million offset by payments on long-term financing obligations of $121,000. The cash provided by financing activities in the six months ended June 30, 2012 was primarily due to the sale and issuance of common stock of $709,000 offset by payments on long-term financing obligations of $98,000.

Operating Capital Requirements

We anticipate that we will continue to generate significant operating losses for the next several years as we incur expenses related to the research and development of our HyperAcute immunotherapy and IDO pathway inhibitor product candidates, build commercial capabilities and expand our corporate infrastructure. Including the funds received from our IPO and our follow-on public offering, we believe that we have sufficient cash and cash equivalents and certificates of deposit to fund our operations through at least the end of 2014.

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We may seek to sell additional equity or debt securities or obtain a credit facility if our available cash and cash equivalents are insufficient to satisfy our liquidity requirements or if we develop additional opportunities to do so. The sale of additional equity and debt securities may result in additional dilution to our 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.

Contractual Obligations and Commitments

On May 30, 2013, we entered into a Standard Design-Build Agreement, or the Story Agreement, with Story Construction Co. to provide temporary remodeling services with respect to approximately 11,800 square feet of existing manufacturing and quality control space at our headquarters in Ames, Iowa. Our obligations under the Story Agreement constitute a purchase obligation of approximately $1.0 million. The full amount is due upon substantial completion of the work, which the Story Agreement contemplates to be less than one year following the date of the Story Agreement. The Story Agreement does not affect our contractual lease obligations or other contractual obligations. There are no other 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 15, 2013.

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 June 30, 2013 and December 31, 2012, we had cash and cash equivalents and certificates of deposit of $59.3 million and $21.7 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.

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Our long-term debt and our capital lease obligations bear interest at fixed rates. Any change in interest rates would have an immaterial (or no) impact on our financial statements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by paragraph (b) of Rules 13a-15 and 15d-15 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, an evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer (Chief Executive Officer) and principal financial officer (Chief Financial Officer), of the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, our management, including our principal executive officer and principal financial officer, concluded that our disclosure controls and procedures were effective as of June 30, 2013 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

No Changes in Internal Control Over Financial Reporting

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

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PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

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 risks and uncertainties. Our actual results could differ significantly 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 HyperAcute Pancreas. If we fail to complete, or demonstrate safety and efficacy in, clinical trials, fail to obtain regulatory approval or fail to successfully commercialize HyperAcute Pancreas, 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 HyperAcute Pancreas. The United States Food and Drug Administration, or FDA, must approve HyperAcute Pancreas before it can be marketed or sold. Our ability to obtain FDA approval of HyperAcute Pancreas depends on, among other things, completion of our Phase 3 clinical trial, whether our Phase 3 clinical trial of HyperAcute Pancreas demonstrates statistically significant achievement of the clinical trial endpoints with no significant safety issues and whether the FDA agrees that the data from our Phase 3 clinical trial of HyperAcute Pancreas is sufficient to support approval. The final results of our Phase 3 clinical trials of HyperAcute Pancreas 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 HyperAcute Pancreas. 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 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 our HyperAcute Pancreas product candidate, 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 HyperAcute Pancreas 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 HyperAcute Pancreas to be approved as a marketable drug. Patients in our Phase 3 study who do not receive HyperAcute Pancreas 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 HyperAcute Pancreas have results which are better than the results predicted by the other

large studies, we may not demonstrate a sufficient benefit from the HyperAcute Pancreas to allow 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, 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 HyperAcute Pancreas 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 HyperAcute Pancreas 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 HyperAcute Pancreas 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 New Drug Application, or NDA, 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 HyperAcute Pancreas Phase 3 clinical trial will be adequate to demonstrate the safety and efficacy of HyperAcute Pancreas 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 HyperAcute Pancreas 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 HyperAcute Pancreas 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 HyperAcute Pancreas Phase 3 clinical trial, or whether HyperAcute Pancreas will receive any regulatory approvals as a result of the SPA agreement or the HyperAcute Pancreas Phase 3 clinical trial. Therefore, significant uncertainty remains regarding the clinical development and regulatory approval process for HyperAcute Pancreas 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 Investigational New Drug applications, or 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. If we do not accurately evaluate the scientific and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements 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, and 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:

- 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;
- slower than expected patient enrollment or lack of a sufficient number of patients that meet the enrollment criteria for our clinical trials;
- patients may not complete clinical trials due to safety issues, side effects, dissatisfaction with the product candidate, or other reasons;
- 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;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy and guidelines;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- 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 product candidates prior to FDA approval. If the delays or costs are significant, our financial results and ability to commercialize the HyperAcute product candidates, indoximod 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:

- 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 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 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 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 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 and seek FDA approval for our production process simultaneously with seeking approval for the marketing and sale of our HyperAcute Pancreas product candidate. 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 partners 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 partner 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. The loss of his 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 in part by expanding our current facilities. This activity 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.

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. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of each Biologics License Application, or BLA, and each 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 and our contract manufacturer for NLG-919, one of our IDO pathway inhibitor candidates, 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 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 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 for NLG-919, we are 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 will rely upon contract manufacturers for indoximod, and for components of the HyperAcute product candidates, for commercial sale if any are approved for sale. In addition, we currently rely on a contract manufacturer for supply of NLG-919 for preclinical studies and, if our IND is approved, we may rely on a contract manufacturer for clinical trials.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 or finished HyperAcute product candidates, indoximod or NLG-919. 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, and may incur substantial costs to develop the capability to manufacture products at commercial scale. Any prolonged delay or interruption in the operations of our facilities or our 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 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 use hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

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

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. 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 our insurance policies or any losses may be excluded under our insurance policies. Certain events, such as natural disasters, fire, political disturbances, sabotage or business accidents, which could impact our current or future facilities, could have a significant negative impact on our operations by disrupting our product development efforts until such time as we are able to repair our facility or put in place third-party contract manufacturers to assume this manufacturing role.

We have experienced bacterial and mycoplasm contaminations in lots produced at our facilities, and we destroyed the contaminated lots and certain overlapping lots. We may experience additional contaminated lots at our facilities, and we will destroy any contaminated lots that we detect, which could result in significant delay or additional expense in

our operations.

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

Our facilities are located in Ames, Iowa, which is susceptible to floods and tornados, and our facilities are therefore vulnerable to damage or disruption from floods and tornados. We are also vulnerable to damage from other types of disasters, such as power loss, fire and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. We currently carry business personal property insurance in the amount of $9.5 million in the aggregate, but this policy

does not cover disasters such as floods and earthquakes. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition.

Risks Relating to Regulation of Our Industry

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

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

Regardless of how much time and resources we devote to development of a product candidate, there can be no assurance that regulatory approval will be obtained for that product candidate. To date, the FDA has approved only one active cellular cancer immunotherapy product, even though several have been, and currently are in, clinical development. Further, even if such regulatory approval is obtained, we, our products and any contract manufacturers or commercial collaborators of ours will be subject to continual regulatory review in both the United States and other countries. Later discovery of previously unknown problems with regard to a product, distributor or manufacturer may result in restrictions, including withdrawal of the product from the market and/or disqualification or decertification of the distributor or manufacturer.

We cannot predict when, if ever, we might submit for regulatory review our product candidates currently under development. Once we submit our potential products for review, there can be no assurance that regulatory approvals for any pharmaceutical products developed by us will be granted on a timely basis, if at all.

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

Even if regulatory approval were obtained, it would be limited as to the indicated uses for which the product may be promoted or marketed. A marketed product, its manufacturer and the facilities in which it is manufactured are subject to continual review and periodic inspections. If marketing approval is granted, we would be required to comply with FDA requirements for manufacturing, labeling, advertising, record keeping and reporting of adverse experiences and other information. In addition, we would be required to comply with federal and state anti-kickback and other health care fraud and abuse laws that pertain to the marketing of pharmaceuticals. Failure to comply with regulatory requirements and other factors could subject us to regulatory or judicial enforcement actions, including product recalls or seizures, injunctions, withdrawal of the product from the market, civil penalties, criminal prosecution, refusals to

approve new products and withdrawals of existing approvals, as well as enhanced product liability exposure, any of which could have a material adverse effect on our business, financial condition and results of operations. Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, manufacturing and pricing. Non-compliance with these requirements could result in enforcement actions or penalties or could delay introduction of our products in certain countries.

The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement outside the United States vary greatly from country to country. The time required to obtain approvals outside the United States may differ from that required to obtain FDA approval. We may not obtain foreign regulatory approvals on a timely basis, or at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products and may have a material adverse effect on our results of operations and financial condition.

We are also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, results of operations, financial condition, cash flow and future prospects.

The availability and amount of reimbursement for our product candidates, if approved, and the manner in which government and private payors may reimburse for our potential product, are uncertain.

In both United States and foreign markets, sales of our proposed products will depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Our future levels of revenues and profitability may be affected by the continuing efforts of governmental and third party payors to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition and results of operations.

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

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

The biopharmaceutical industry is subject to significant regulation and oversight in the United States, in addition to approval of products for sale and marketing.

In addition to FDA restrictions on marketing of biopharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim

paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims

laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition and results of operations.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. We expect to face pricing pressure globally from managed care organizations, institutions and government agencies and programs, which could negatively affect the sales and profit margins for our HyperAcute product candidates, indoximod or 1-methyl-D-tryptophan (D-1MT) or any other of our product candidates that are approved for marketing.

In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. Most recently, in March 2010 the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;
- a licensure framework for follow-on biologic products, also known as biosimilars;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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

such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our

business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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

Financial Risks

We have a history of net losses. We expect to continue to incur increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

We are not profitable and have incurred significant net losses in each year since our inception, including net losses of $23.3 million, $18.1 million and $16.2 million for the years ended December 31, 2012, 2011 and 2010, respectively and a net loss of $15.0 million for the six months ended June 30, 2013. As of June 30, 2013, we had an accumulated deficit of $119.8 million. Our losses have resulted principally from costs incurred in our research and development activities. We anticipate that our operating losses will substantially increase over the next several years as we expand our discovery, research and development activities, including the Phase 2 and Phase 3 clinical development of the HyperAcute product candidates and Phase 2 clinical development of indoximod.

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

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

Development of our HyperAcute product candidates, indoximod and any other product candidates will require substantial additional funds to conduct research, development and clinical trials necessary to bring such product candidates to market and to establish manufacturing, marketing and distribution capabilities. Our future capital requirements will depend on many factors, including, among others:

- the scope, rate of progress, results and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, rate of progress and costs of our manufacturing development and commercial manufacturing activities;
- the cost, timing and outcomes of regulatory proceedings (including FDA review of any BLA or NDA we file);
- payments required with respect to development milestones we achieve under our in-licensing agreements;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the costs associated with commercializing our product candidates, if they receive regulatory approval;
- the cost and timing of developing our ability to establish sales and marketing capabilities;
- competing technological efforts and market developments;
- changes in our existing research relationships;
- our ability to establish collaborative arrangements to the extent necessary;
- revenues received from any existing or future products; and
- payments received under any future strategic partnerships.

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We anticipate that we will continue to generate significant losses for the next several years as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, develop our pipeline and expand our corporate infrastructure. We believe that our existing cash and cash equivalents and certificates of deposit, including the proceeds from our follow-on public offering that closed on February 4, 2013, will allow us to fund our operating plan through at least the end of 2014. However, our operating plan may change as a result of factors currently unknown to us.

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

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

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

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

We have a forgivable loan that may have to be repaid if we do not achieve job creation goals.

In March 2010, we entered into a $400,000 forgivable loan agreement with the City of Ames, Iowa and the Ames Chamber of Commerce, in order to help finance the construction of new facilities within the Ames city limits. In the absence of a default, there are no principal or interest payments due until the expected completion date for the project, which is March 10, 2015. The project calls for us to create or retain at least 70 full-time jobs located in Ames, Iowa as of March 10, 2012 and to create or retain at least 150 full-time positions located in Ames, Iowa as of March 10, 2015. The agreement also calls for us to enter into a five-year building lease with option for extension for an additional five years of not less than 20,000 square feet within the corporate limits of the City of Ames by March 10, 2015. If, as of March 10, 2015, we have fulfilled the terms of the loan agreement, the loan will be forgiven. If on March 10, 2012 and March 10, 2015, we have failed to create or retain at least 70 full-time jobs and 150 full-time jobs in Ames, Iowa, respectively, we will be required to repay approximately $3,100 per job not created or retained following the respective date. As of June 30, 2013, we had created or retained an aggregate of 93 full-time jobs in Ames, Iowa, and prior to March 10, 2012, we had created or retained at least 70 full-time jobs in Ames, Iowa. As of June 30, 2013, $300,000 of the total $400,000 forgivable loan was advanced to us with the final $100,000 pending certification to the City of Ames regarding the creation of a threshold level of jobs. In the event of default, including failure to repay any amounts under the loan when due, we will be required to repay the note including 6.5% interest per annum beginning at the date of default.

We have not yet met all the job creation requirements of the City of Ames loan. If we cannot or do not comply with these and all other requirements under this loan, we may be obligated to pay principal and interest on this loan immediately. If we are unable to meet our obligations to service our debt and fund our business, we may be forced to reduce or delay capital expenditures, seek additional debt financing or equity capital, restructure or refinance our debt or sell assets. We cannot assure you that we would be able to obtain additional financing, refinance existing debt or sell assets on satisfactory terms or at all.

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

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

Through our subsidiary, BioProtection Systems Corporation, or BPS, we also have ongoing contracts and grants with the United States Department of Defense and National Institutes of Health, respectively. The termination of a United States government grant, contract or relationship as a result of our failure to satisfy any of our obligations under the grants or contracts would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, there can be no assurance that we will secure comparable contracts with, or grants from, the United States government in the future.

Risks Relating to Competitive Factors

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

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

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

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

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

Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success of any products we may commercialize.

The biopharmaceutical industry is highly competitive. There are many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer. Given the significant unmet patient need for new therapies, oncology is an area of focus for large and small companies as well as research institutions. As a result, there are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. In addition, there are a number of multinational pharmaceutical companies and large biotechnology companies currently marketing or pursuing the development of products or product candidates targeting the same cancer indications as our product candidates, and several large public biopharmaceutical companies have approved or are developing cancer immunotherapy products, including Dendreon Corporation, Bristol-Myers Squibb Company, GlaxoSmithKline plc, Merck & Co., Merck KGaA and Sanofi-Aventis.

There are several marketed products indicated for pancreatic cancer, including Eli Lilly and Company's Gemzar®, Astellas Pharma's Tarceva®, Teva Pharmaceutical Industries Limited's streptozocin, and fluorouracil, or 5-FU, and mitomycin which are marketed by several generic pharmaceutical firms. There are numerous marketed therapeutics indicated for NSCLC, including Roche AG's Avastin®, Eli Lilly's Alimta® and Gemzar, Astellas Pharma's Tarceva, AstraZeneca's Iressa®, and Sanofi-Aventis' Taxotere and Eloxatin, as well as generically available platinum-based chemotherapeutics (cisplatin and carboplatin) and mitotic

inhibitors (paclitaxel and venorelbine). There are also several marketed therapeutics indicated for advanced melanoma, including Merck's Intron A and Novartis/Prometheus Laboratories' Proleukin®, as well as cisplatin and dacarbazine, which are available generically. Bristol-Myers Squibb's immunotherapy ipilimumab was recently approved by the FDA as was Roche/Daiichi Sankyo's drug, vemurafenid.

In addition, there are a number of companies with active clinical trials ongoing in pancreatic cancer including AB Science SA, Amgen Inc., Astellas Pharma, BioSante Pharmaceuticals, Inc., Celgene Corporation, Immunomedics, Inc., Lorus Therapeutics Inc., Sanofi-Aventis and Threshold Pharmaceuticals, Inc., a number of companies with active clinical trials ongoing in NSCLC, including Abbott Laboratories, Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, BioNumerik Pharmaceuticals, Inc., Celgene, GlaxoSmithKline, NovaRx Corporation, Onyx Pharmaceuticals, Inc., Pfizer Inc. and Regeneron Pharmaceuticals, Inc., and a number of companies with active clinical trials ongoing in advanced melanoma, including Amgen, Astellas Pharma, Eli Lilly, Onyx, Roche, Synta Pharmaceuticals Corp., and Vical Inc. among other companies.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the significant expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. There are many different approaches to using immunotherapies to treat cancer, including anti-idiotype, whole cell, DNA, peptide/antigen, viral, tumor lysate, shed antigens, and dendritic cell. Cancer immunotherapies are also distinguished by whether or not they are derived from autologous or allogeneic sources. Each of the various approaches to cancer immunotherapy have potential advantages and disadvantages based on factors such as their immunostimulatory mechanisms, formulation characteristics, manufacturing requirements, and treatment regimens. We also compete with other clinical-stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Delay in recruiting clinical trial participants could adversely affect our ability to bring a product to market prior to our competitors. Further, research and discoveries by others may result in breakthroughs that render our HyperAcute product candidates, indoximod or our other potential products obsolete even before they begin to generate any revenue.

In addition, our competitors may obtain patent protection or FDA approval and commercialize products more rapidly than we do, which may impact future sales of any of our products that receive marketing approval. If the FDA approves the commercial sale of any of our products, we will also be competing with respect to marketing capabilities and manufacturing efficiency, areas in which we have limited or no experience. We expect that competition among products approved for sale will be based, among other things, on product efficacy, price, safety, reliability, availability, patent protection, and sales, marketing and distribution capabilities. Our profitability and financial position will suffer if our products receive regulatory approval, but cannot compete effectively in the marketplace.

If any of our product candidates are approved and commercialized, we may face competition from generic products if the product candidate is a small molecule drug, or biosimilars if the product candidate is a biologic. The route to market for generic versions of small molecule drugs was established with the passage of the Hatch-Waxman Amendments in 1984 and for biosimilars with the passage of the PPACA in March 2010. The PPACA establishes a pathway for the FDA approval of follow-on biologics and provides 12 years of marketing exclusivity for reference products and an additional six months of exclusivity if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

Our biodefense product candidates face significant competition for United States government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. Competitors include Emergent BioSolutions,

SIGA Technologies, AVI Biopharma, Pharmathene, Acambis, Bavarian Nordic AS, and Novartis. Academic institutions, government agencies, private research organizations and public research organizations are also conducting research and filing patents toward commercialization of products. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

Our products may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any.

Even if the HyperAcute product candidates, indoximod or any of our other potential products are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our products, if successfully developed, will compete with a number of traditional products and immunotherapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third party payors.

Risks Relating to Our Arrangements with Third Parties

We rely on third parties to conduct our preclinical studies and our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.

We do not have the ability to conduct preclinical studies or clinical trials independently for our product candidates. We must rely on third parties, such as contract research organizations, medical institutions, academic institutions, clinical investigators and contract laboratories, to conduct our preclinical studies and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with GLP for conducting and recording the results of our preclinical studies and cGCP for conducting, monitoring, recording and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with cGCP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

If we fail to enter into any needed collaboration agreements for our product candidates, we may be unable to commercialize them effectively or at all.

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

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

If we enter into a collaboration agreement we consider acceptable, the collaboration may not proceed as quickly, smoothly or successfully as we plan. The risks in a collaboration agreement include the following:

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

If we enter into one or more collaborations for our HyperAcute product candidates, indoximod or any of our other product candidates, we will be dependent on our collaborators' performance of their responsibilities and their cooperation with us. Our collaborators may not perform their obligations under our agreements with them or otherwise cooperate with us. We cannot control whether our collaborators will devote the necessary resources to the activities contemplated by our collaborative agreements, nor can we control the timing of their performance. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us. Disputes may arise between us and our collaborators that delay the development and commercialization of our product candidates that are difficult and costly to resolve, or may not be resolved. In addition, a collaborator for the HyperAcute product candidates or indoximod may have the right to terminate the collaboration at its discretion. Any termination may require us to seek a new collaborator, which we may not be able to do on a timely basis, if at all, or require us to delay or scale back the commercialization efforts. The occurrence of any of these events could adversely affect the commercialization of the HyperAcute product candidates or indoximod and materially harm our business and stock price by delaying the sale of any product that may be approved by the FDA, by slowing the growth of such sales, by reducing the profitability of the product and/or by adversely affecting the reputation of the product.

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

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

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

We may, in the future, periodically explore a variety of possible strategic partnerships in an effort to gain access to additional product candidates or resources. At the current time, we cannot predict what form such a strategic partnership might take. We are likely to face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be complicated and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

If we enter into one or more strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to unfavorable terms.

Any future strategic partnerships we enter into could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our existing stockholders' percentage ownership;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of our product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
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strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;

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

- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement;
- strategic partners could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic partners could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Relating to Protecting Our Intellectual Property

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

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

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

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

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

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

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office has developed regulations and procedures to govern administration of the Leahy-Smith Act, but many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor to file provisions, only became effective 18 months after its enactment. Accordingly, it is not clear what, if any, impact

the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

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

Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of others.

Under the Abbreviated New Drug Application provisions of U.S. law, after four years from the date marketing approval is granted to us by the FDA for a patented drug, a generic drug company may submit an Abbreviated New Drug Application to the FDA to obtain approval to market in the United States a generic version of the drug patented by us. If approval were given to the generic drug company, we would be required to promptly initiate patent litigation to prevent the marketing of such generic version prior to the normal expiration of the patent. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any generic drug would be found to infringe our patents.

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

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

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

Risks Relating to Our Exposure to Litigation

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

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan, and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper

administration of the product candidate, or other factors. Many of these patients are already seriously ill and are therefore particularly vulnerable to further illness or death.

We currently carry clinical trial liability insurance in the amount of $5 million in the aggregate, but there can be no assurance that we will be able to maintain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Similar risks would exist upon the commercialization or marketing of any products by us or our partners.

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

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

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biopharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in this “Risk Factor,” section of this Quarterly Report on Form 10-Q, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management’s attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

Risks Related to Ownership of Our Common Stock

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

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

- new products, product candidates or new uses for existing products introduced or announced by our strategic partners, or our competitors, and the timing of these introductions or announcements;
- actual or anticipated results from and any delays in our clinical trials, including our Phase 3 clinical trial of our HyperAcute Pancreas product candidate, as well as results of regulatory reviews relating to the approval of our product candidates;
- variations in the level of expenses related to any of our product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our clinical research organizations and clinical trial sites;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- conditions or trends in the biotechnology and biopharmaceutical industries;
-

actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
actual and anticipated fluctuations in our quarterly operating results;

- the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- deviations from securities analysts' estimates or the impact of other analyst ratings downgrades by any securities analysts who follow our common stock;
- other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;
- changes in accounting principles;
- discussion of us or our stock price by the financial and scientific press and in online investor communities;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

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

As of June 30, 2013, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 44.2% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after June 30, 2013. These stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our Board of Directors, future issuances of our common stock or other securities, declarations of dividends on our common stock and approval of other significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock. In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares may be distributed and subsequently voted.

A significant portion of our total outstanding shares of common stock is restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Certain holders of outstanding shares of our common stock that have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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

As a public company, we incur significant legal, accounting and other expenses to comply with reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and The NASDAQ Stock Market, or NASDAQ. Meeting the requirements of these rules and regulations entails significant legal and financial compliance costs, makes some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel devote a substantial amount of time to these compliance requirements. In addition, these rules and regulations may make it more difficult and more expensive for

us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our ability to produce accurate financial statements and on our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we are required to publish a report by our management on our internal control over financial reporting. The internal control report must contain (a) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (b) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (c) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (d) a statement that our independent registered public accounting firm has issued an attestation report on internal control over financial reporting.

To achieve compliance with Section 404, we have engaged in a process to document and evaluate our internal control over financial reporting, which has been both costly and challenging. To maintain compliance on an ongoing basis, we will need to dedicate internal resources, engage outside consultants and adopt a detailed work plan to (a) assess and document the adequacy of internal control over financial reporting, (b) take steps to improve control processes where appropriate, (c) validate through testing that controls are functioning as documented, and (d) implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we can provide no assurance as to our, or our independent registered public accounting firm's, conclusions with respect to the effectiveness of our internal control over financial reporting under Section 404. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

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

Provisions of our certificate of incorporation, our by-laws or Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interest. These provisions include:

- the division of our Board of Directors into three classes with staggered, three-year terms;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- limitation on the ability of stockholders to remove directors or amend our by-laws; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the

date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

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

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

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

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

Based on Section 382 ownership change analyses, we believe that, from its inception through December 31, 2011, NewLink experienced Section 382 ownership changes in September 2001 and March 2003 and our subsidiary 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 our subsidiary.

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 have caused or will cause another ownership change to occur, and the conclusions will depend on information that currently may not be available to us. Any such change could result in significant limitations on all of our net operating loss carryforwards and other tax attributes.

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

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

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

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We began implementation of a new accounting system in the second quarter of 2013, and we may experience unforeseen difficulties or delays in implementing the new system.

We began implementation of a new accounting system in the second quarter of 2013 and expect it to be implemented for financial reporting purposes by the end of the third quarter. If we encounter unforeseen difficulties in implementing the system, we could experience delays in financial reporting, weaknesses in our internal controls or

unanticipated expenses.

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ITEM 1. LEGAL PROCEEDINGS

None.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

On November 16, 2011, we completed our initial public offering, or IPO, raising a total of $37.6 million in net proceeds after deducting underwriting discounts and commissions of $3.0 million and offering expenses of $2.9 million.

As of June 30, 2013, we had invested the net proceeds from the IPO in cash equivalents, including money market funds, treasury bills and certificates of deposit. We intend to invest these funds in the future in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government in accordance with our investment policy. Through June 30, 2013, we have used approximately $31.8 million of the net proceeds from the initial public offering to fund our Phase 3 clinical trial and related development activities for HyperAcute Pancreas, clinical and related development activities for our other HyperAcute immunotherapy and IDO pathway inhibitor product candidates, other research and development activities and other working capital expenditures and general corporate purposes. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus for the offering filed with the SEC pursuant to Rule 424(b).

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. REMOVED

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

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SIGNATURES

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

NEWLINK GENETICS CORPORATION

By: /s/ Charles J. Link, Jr.
Charles J. Link, Jr.
Chief Executive Officer
(Principal Executive Officer)
Date: August 8, 2013

By: /s/ Gordon H. Link, Jr.
Gordon H. Link, Jr.
Chief Financial Officer and Secretary
(Principal Financial and Accounting Officer)
Date: August 8, 2013

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

Exhibit Number		Description	Incorporated By Reference Form	Filing Date	Number	Filed Herewith
3.1		Amended and Restated Certificate of Incorporation filed on November 16, 2011	8-K	11/18/2011	3.1	
3.2		Amended and Restated Bylaws	8-K	11/18/2011	3.2	
4.1		Form of the Registrant’s Common Stock Certificate	S-1/A	10/26/2011	4.1	
4.2		Reference is made to Exhibits 3.1 and 3.2	8-K	11/18/2011	3.1,3.2	
4.3		Amended and Restated Investor Rights Agreement by and between the Company and certain holders of the Company’s capital stock dated as of December 1, 2010	10-Q	5/10/2012	4.3	
10.1		Story Construction Contract				X
10.2		Memorandum of Agreement; Addendum to the Lease Between ISU Research Park Corporation and NewLink Genetics Corporation Dated March 1, 2010				X
10.3		2010 Non-Employee Directors' Stock Award Plan, as amended	8-K	5/14/2013	10.1	
10.4		2010 Employee Stock Purchase Plan, as amended	8-K	5/14/2013	10.2	
10.5		2013 Target Bonus Awards	8-K	4/5/2013	10.1	
31.1		Certification of principal executive officer required by Rule 13a-14(a) / 15d-14(a)				X
31.2		Certification of principal financial officer required by Rule 13a-14(a) / 15d-14(a)				X
32.1	#	Section 1350 Certification				X
101.INS	‡	XBRL Instance Document				X
101.SCH	‡	XBRL Taxonomy Extension Schema Document (furnished electronically herewith)				X
101.CAL	‡	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	‡	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	‡	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	‡	XBRL Taxonomy Extension Presentation Linkbase Document				X

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

‡ XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.