HEAT BIOLOGICS, INC.
Form 10-Q
September 05, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2013

OR

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: 001-35994

Heat Biologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2844103**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
100 Europa Drive	**27517**
Chapel Hill, NC	*(Zip Code)*

(Address of principal executive offices)

(919) 240-7133

(Registrant's telephone number, including area code)

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 o No þ

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 ¨ 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.

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	þ
(Do not check if smaller reporting company)			

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

As of August 30, 2013 there were 6,194,719 shares of Common Stock, $0.0002 par value per share, outstanding.

HEAT BIOLOGICS, INC.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Forward-looking statements are not guarantees of future performance and our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements include, but are not limited to, our ability to raise additional capital to support our clinical development program and other operations, our ability to develop products of commercial value and to identify, discover and obtain rights to additional potential product candidates, our ability to protect and maintain our intellectual property and the ability of our licensors to obtain and maintain patent protection for the technology or products that we license from them, the outcome of research and development activities, our reliance on third-parties, competitive developments, the effect of current and future legislation and regulation and regulatory actions, as well as other risks described more fully in this Quarterly Report on Form 10-Q.

As a result of these and other factors, we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I FINANCIAL INFORMATION

ITEM 1.

FINANCIAL STATEMENTS

HEAT BIOLOGICS, INC.

(A development stage company)

Condensed Consolidated Balance Sheets

	June 30, 2013 (unaudited)	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	$ 3,015,738	$ 5,030
Related party receivable	16,446	9,571
Prepaid expenses and other current assets	500,376	58,436
Total Current Assets	3,532,560	73,037
Property and Equipment, net	9,838	10,782
Other Assets		
Restricted cash	26,366	26,214
Debt issuance costs, net	24,589	28,229
Deposits	9,320	9,320
Total Other Assets	60,275	63,763
Total Assets	$ 3,602,673	$ 147,582
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities		
Accounts payable	$ 1,319,036	$ 505,471
Accrued expenses and other payables	211,638	129,208
Accrued interest	43,509	13,763
Notes payable - current portion	150,139	66,806
Total Current Liabilities	1,724,322	715,248
Long Term Liabilities		
Notes payable - less current portion	574,861	658,194
Convertible notes payable		197,099
Preferred stock warrants liability	193,120	92,150
Total Liabilities	2,492,303	1,662,691

Stockholders' Equity (Deficit)		
Series 1 preferred stock, $.0001 par value; 112,500 shares authorized, 112,500 shares issued and outstanding	11	11
Series A preferred stock, $.0001 par value; 2,000,000 shares authorized, 1,863,128 shares issued and outstanding	186	186
Series B-1 preferred stock, $.0001 par value; 4,100,000 shares authorized, 1,891,419 shares issued and outstanding at June 30, 2013 (unaudited)	189	
Common stock, $.0002 par value; 50,000,000 shares authorized, 2,144,542 shares issued and 1,861,145 and 1,858,971 shares outstanding at June 30, 2013 (unaudited) and December 31, 2012, respectively	405	405
Additional paid in capital	9,583,798	4,495,832
Deficit accumulated during the development stage	(8,319,912)	(5,935,282)
Total Stockholders' Equity (Deficit) - Less Non-Controlling Interest	1,264,677	(1,438,848)
Non-Controlling Interest	(154,307)	(76,261)
Total Stockholders' Equity (Deficit)	1,110,370	(1,515,109)
Total Liabilities and Stockholders' Equity (Deficit)	$ 3,602,673	$ 147,582

See Notes to Condensed Consolidated Financial Statements

HEAT BIOLOGICS, INC.

(A development stage company)

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended, June 30,		Six Months Ended June 30,		Period from June 10, 2008 (inception) to June 30,
	2013	2012	2013	2012	2013
Grant awards	$	$ 3,110	$	$ 3,110	$ 585,589
Operating expenses:					
Research and development	688,979	178,410	1,129,268	349,175	4,486,750
Clinical and regulatory	454,934	100,312	516,991	147,119	944,834
General and administrative	438,180	360,394	706,316	586,451	3,001,842
Total operating expenses	1,582,093	639,116	2,352,575	1,082,745	8,433,426
Loss from operations	(1,582,093)	(636,006)	(2,352,575)	(1,079,635)	(7,847,837)
Interest income	1		2		689
Other expense	(60,324)	1,132	(49,962)	(528)	(58,745)
Interest expense	(31,799)	(13,856)	(60,141)	(15,615)	(279,602)
Total non-operating expenses	(92,122)	(12,724)	(110,101)	(16,143)	(337,658)
Loss from continuing operations	(1,674,215)	(648,730)	(2,462,676)	(1,095,778)	(8,185,495)
Loss from discontinued operations		(19,029)		(20,129)	(288,724)
Net loss	(1,674,215)	(667,759)	(2,462,676)	(1,115,907)	(8,474,219)
Net loss - non-controlling interest	(53,441)	(7,914)	(78,046)	(14,378)	(154,307)
Beneficial conversion charge			(2,300,000)		(2,300,000)
Net loss attributable to	$ (1,620,774)	$ (659,845)	$ (4,684,630)	$ (1,101,529)	$ (10,619,912)

common stockholders					
Net loss per share attributable to common stockholders basic and diluted	$ (0.92)	$ (0.38)	$ (2.55)	$ (0.64)	
Weighted-average number of common shares used in net loss per share attributable to common stockholders basic and diluted	1,761,962	1,739,135	1,840,048	1,734,370	2,054,824

See Notes to Condensed Consolidated Financial Statements

HEAT BIOLOGICS, INC.

(A development stage company)

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Six Months Ended June 30,		June 10, 2008 (Inception) to June 30,
	2013	**2012**	**2013**
Cash Flows from Operating Activities			
Net loss	$ (2,462,676)	$ (1,115,907)	$ (8,474,219)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	944	1,525	4,155
Amortization of debt issuance costs	3,640	9,625	102,153
Remeasurement of fair value of preferred stock warrants liability	100,970	(1,300)	105,550
Non-cash consideration for rent			15,624
Stock based compensation	183,575	100,079	537,610
Increase (decrease) in cash arising from changes in assets and liabilities:			
Related party receivable	(6,875)		(16,446)
Prepaid expenses and other current assets	(441,940)	(7,414)	(500,376)
Restricted cash	(152)	460	(26,366)
Deposits		200	(9,320)
Accounts payable	616,466	(16,323)	1,121,937
Accrued expenses and other payables	82,430	41,942	211,638
Accrued interest	29,746	5,530	94,780
Net Cash Used by Operating Activities	(1,893,872)	(981,583)	(6,833,280)
Cash Flows from Investing Activities			
Purchase of property and equipment		(1,780)	(13,993)
Net Cash Used in Investing Activities		(1,780)	(13,993)
Cash Flows from Financing Activities			
Borrowings on notes payable		225,000	950,000
Borrowings on line of credit		72,567	273,427
Payments on notes payable			(225,000)
Payments on line of credit			(273,427)
Issuance of convertible notes payable, net of issuance costs			2,781,636

Issuance of common stock			11,790
Issuance of series A preferred stock		1,083,334	1,487,589
Issuance of series B-1 preferred stock	5,050,090		5,050,090
Stock issuance costs	(145,510)	(695)	(193,094)
Net Cash Provided by Financing Activities	4,904,580	1,380,206	9,863,011
Net Increase in Cash and Cash Equivalents	3,010,708	396,843	3,015,738
Cash and Cash Equivalents Beginning of Period	5,030	98,646	
Cash and Cash Equivalents End of Period	$ 3,015,738	$ 495,489	$ 3,015,738

See Notes to Condensed Consolidated Financial Statements

HEAT BIOLOGICS, INC.

(A development stage company)

Condensed Consolidated Statements of Cash Flows (Continued)

(unaudited)

	Six Months Ended June 30,		June 10, 2008 (Inception) to June 30,
	2013	**2012**	**2013**
Supplemental Disclosure for Cash Flow Information			
Interest paid	$ 17,445	$	$ 92,129
Supplemental Schedule of Noncash Investing and Financing Activities			
Beneficial conversion charge	$ 2,300,000	$	$ 2,300,000
Issuance of preferred stock warrants and debt issuance costs	$	$	$ 87,570
Conversion of convertible notes payable into accounts payable	$ 197,099	$	$ 197,099
Cancellation of common stock	$	$	$ 65
Non-cash consideration for rent	$	$	$ 15,624

See Notes to Condensed Consolidated Financial Statements

HEAT BIOLOGICS, INC.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Basis of presentation

The accompanying unaudited condensed consolidated balance sheet as of June 30, 2013, condensed consolidated statements of operations for the three and six month periods ended June 30, 2013 and 2012, the condensed consolidated statements of cash flows for the six month periods ended June 30, 2013 and 2012, and the cumulative period from inception (June 10, 2008) to June 30, 2013 of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting only of normal and recurring adjustments, considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimated. Additionally, operating results for the three and six months ended June 30, 2013 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2013. For further information, refer to the financial statements and footnotes included in the Company's Prospectus as filed with the Securities and Exchange Commission ("SEC") under Rule 424(b) of the Securities Act of 1933 on July 24, 2013.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of Heat Biologics, Inc. and its subsidiaries, Heat Biologics I, Inc. (Heat I) and Heat Biologics II, Inc (Heat II), Heat Biologics III, Inc (Heat III), Heat Biologics IV, Inc. (Heat IV) and Heat Biologics GmbH. All significant intercompany accounts and transactions have been eliminated in consolidation. At December 31, 2012 and June 30, 2013 (unaudited), Heat held a 92.5% controlling interest in Heat I and accounts for its less than 100% interest in the condensed consolidated financial statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interests as a component of stockholders equity (deficit) on its condensed consolidated balance sheets and reports non-controlling interest net income (loss) under the heading net income (loss) non-controlling interest in the condensed consolidated statements of operations. In June 2012, the Company sold its entire 92.5% interest in Heat II. The operations of Heat II through June 25, 2012, including fiscal year 2012 and 2011, and inception to date, are presented in the accompanying condensed consolidated statements of operations as a loss from discontinued operations.

2. Fair Value of Financial Instruments

The carrying amount of certain of the Company s financial instruments, including prepaid expenses and other current assets, deposits, accounts payable and accrued expenses and other payables approximate fair value due to their short maturities. The carrying value of the Company s notes payable and convertible notes payable approximated fair value because the interest rates under those obligations approximate market rates of interest available to the Company for similar instruments.

As a basis for determining the fair value of certain of the Company s financial instruments, the Company utilizes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level I Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level II Observable inputs, other than Level I prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level III Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

HEAT BIOLOGICS, INC.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

2. Fair Value of Financial Instruments (Continued)

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The Company s financial instruments that are measured at fair value on a recurring basis consist only of the preferred stock warrant liability. The Company s preferred stock warrant liability is classified within Level III of the fair value hierarchy.

The change in the fair value of the Level III preferred stock warrant liability is summarized below:

Fair value at December 31, 2012	$	92,150
Issuances		
Change in fair value during the period		100,970
Fair value at June 30, 2013	$	193,120

3. Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered more-likely-than-not that the position taken will be sustained by a taxing authority. As of June 30, 2013 and December 31, 2012, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company s effective income tax rate associated with these items. The Company s policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of income. As of June 30, 2013 and December 31, 2012, the Company had no such accruals.

4. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2013	December 31, 2012
Compensation and related benefits	$ 160,524	$ 105,927
Accrued patent fees	23,333	20,000
Professional fees	27,781	3,281
	$ 211,638	$ 129,208

HEAT BIOLOGICS, INC.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

5. Net Loss Per Share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company's potentially dilutive shares, which include convertible preferred stock, outstanding stock options and unvested restricted stock 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 reconciles net loss to net loss applicable to common shareholders:

	Three Months Ended June 30,		Six Months Ended June 30,		Period from June 10,2008 (inception) to June 30,
	2013	**2012**	**2013**	**2012**	**2013**
Net loss	$ (1,674,215)	$ (667,759)	$ (2,462,676)	$ (1,115,907)	$ (8,474,219)
Net loss: Non-controlling interest	(53,441)	(7,914)	(78,046)	(14,378)	(154,307)
Beneficial conversion charge			(2,300,000)		(2,300,000)
Net loss applicable to common stockholders	$ (1,620,774)	$ (659,845)	$ (4,684,630)	$ (1,101,529)	$ (10,619,912)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted	1,761,962	1,739,135	1,840,048	1,734,370	2,054,824
Net loss per share applicable to	$ (0.92)	$ (0.38)	$ (2.55)	$ (0.64)	

common
stockholders basic
and diluted

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect):

	Three Months Ended		Six Months Ended		Period from June 10, 2008 (inception) to
	June 30,		June 30,		June 30,
	2013	2012	2013	2012	2013
Preferred stock	1,682,379	860,017	1,682,379	860,017	1,682,379
Preferred stock warrants	20,549	20,549	20,549	20,549	20,549
Outstanding stock options	644,280	572,637	644,280	572,637	644,280
Unvested restricted stock		7,247		7,247	
Common stock warrants	32,610	32,610	32,610	32,610	32,610

Reverse Stock Split

In May 2013, the Company's board of directors and stockholders approved a 1-for-2.3 reverse stock split of the Company's common stock. The reverse stock split became effective on May 29, 2013. All share and per share amounts in the financial statements have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the increase in par value to additional paid-in capital.

HEAT BIOLOGICS, INC.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

6. Stock-Based Compensation

Restricted Stock

A summary of the Company's unvested restricted stock as of June 30, 2013 and changes during the six months ended June 30, 2013 is as follows:

	Shares		Weighted-Average Grant Date Fair Value
Unvested at December 31, 2012	2,899	$	2.23
Vested	(2,899)	$	2.09
Unvested at June 30, 2013		$	

As of June 30, 2013, all restricted stock has vested and accordingly all stock-based compensation expense related to vested restricted stock has been recognized.

Stock Options

The following is a summary of the stock option activity for the six months ended June 30, 2013:

	Shares		Weighted Average Exercise Price
Outstanding, December 31, 2012	590,047	$	0.71
Granted	72,496	$	8.81
Forfeited	(18,263)	$	0.59
Outstanding, June 30, 2013	644,280	$	1.63

The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2013 was $7.26. The total fair value of stock options that vested during the six months ended June 30, 2013 was approximately $158,000. The fair value of each stock option is estimated on the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions for stock options granted during the six months ended June 30, 2013:

Dividend yield	0.0%
Expected volatility	90%
Risk-free interest rate	1.39-1.5%
Expected lives (years)	5-6

The risk-free interest rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options. The Company used an average historical stock price volatility based on an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms, as the Company did not have any trading history for its common stock. Expected term represents the period that the Company s stock option grants are expected to be outstanding. The Company elected to utilize the simplified method to value stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plans to do so in the future. The forfeiture rate was considered to be none insofar as the historical experience of the Company is very limited. As required by ASC 718, the Company will adjust the estimated forfeiture rate based upon actual experience.

HEAT BIOLOGICS, INC.

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

6. Stock-Based Compensation (Continued)

The Company recognized $183,575 and $100,079 in stock-based compensation expense for the six months ended June 30, 2013 and 2012, respectively for the Company s stock option awards.

The following table summarizes information about stock options outstanding at June 30, 2013:

Options Outstanding			Options Exercisable			Options Vested or Expected to Vest		
Balance as of 6/30/2013	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of 6/30/2013	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of 6/30/2013	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
644,280	8.08	$1.63	457,823	7.62	$0.76	457,823	7.62	$0.76

As of June 30, 2013, the unrecognized stock-based compensation expense related to unvested stock options was approximately $949,000, which is expected to be recognized over a weighted average period of approximately 28 months.

Series B Financing

In March 2013, we sold an aggregate of 1,891,419 shares of our Series B-1 Preferred Stock for gross proceeds of $5,050,090 in our Series B Preferred Stock private placement. All shares of the Series B Preferred Stock, together with accrued dividends, automatically were to convert into shares of our common stock upon the consummation of a

firm commitment underwritten public offering resulting in aggregate net cash proceeds to us of at least $15,000,000 (a Qualified Public Offering). In addition, upon consummation of a Qualified Public Offering, the investors in our Series B-1 Preferred Stock were to be issued shares of our common stock having a value based upon the initial public offering price of $361,668 and our obligation to issue, and the investors, obligation to purchase, Series B-2 Preferred Stock and warrants upon fulfillment of certain conditions specified in our stock purchase agreement dated as of March 25, 2013 entered into in connection with such private placement (the Stock Purchase Agreement) will terminate. See Note 7- Subsequent Events below with respect to the stock issuances that occurred upon consummation of the Qualified Public Offering on July 29, 2013.

7. Subsequent Events

Initial Public Offering

On July 29, 2013, we sold 2,500,000 shares of common stock at a public offering price of $10.00 per share upon the closing of our initial public offering (IPO) with estimated net proceeds of $22.1 million (gross proceeds of $25 million). On August 15, 2013, we sold an additional 100,000 shares of common stock at a public offering price of $10.00 per share pursuant to the partial exercise of the over-allotment option granted to the underwriters resulting in additional gross proceeds to the Company of $1,000,000 and additional net proceeds of $930,000. The total gross proceeds raised from the offering and over-allotment option were $26,000,000, before underwriting discounts and commissions and other offering expenses payable by the Company and the total estimated net proceeds were $23 million. Upon the closing of the IPO, all shares of our then-outstanding preferred stock automatically converted into an aggregate of 1,696,683 shares of common stock. In addition, upon the closing of the IPO, we issued an additional 36,167 shares of our common stock to the Series B Preferred Stockholders as discussed above under Series B Financing and our obligation to issue, and the Series B Preferred Stockholders, obligation to purchase, Series B-2 Preferred Stock under the Stock Purchase Agreement terminated.

On August 27, 2013 we repaid the entire outstanding balance in the amount of $725,000 to Square 1 Bank and the loan agreement with Square 1 Bank was terminated.

On September 3, 2013, the Company received written notification from the underwriters of their partial exercise of the over-allotment option to purchase an additional 100,000 shares of the Company s common stock, at a price to the public of $10.00 per share. The closing is scheduled to occur on September 6, 2013.

ITEM 2.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this quarterly report. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this quarterly report. This discussion should be read in conjunction with the accompanying unaudited condensed consolidated financial statements and the audited condensed consolidated financial statements and notes thereto included in our Prospectus filed with the SEC pursuant to Rule 424 (b) of the Securities Act of 1933 (the Securities Act)on July 24, 2013 (the Prospectus). This discussion may contain forward-looking statements that involve risks and uncertainties. See Forward-Looking Statements.

OVERVIEW

We are a development stage biopharmaceutical company engaged in the development of novel allogeneic, off-the-shelf cellular therapeutic vaccines to combat a wide range of cancers and infectious diseases. Our proprietary *ImPACT* Immune Pan Antigen Cytotoxic Therapy is being designed to deliver live, genetically-modified, irradiated human cells which are reprogrammed to pump out a broad spectrum of cancer-associated antigens together with a potent immune adjuvant called gp96 to educate and activate a cancer patient s immune system to recognize and kill cancerous cells. We intend for our *ImPACT* cells to secrete an antigen-adjuvant complex that generates anti-cancer immune responses in patients by mobilizing and activating cytotoxic killer T cells that target multiple cancer antigens, thus harnessing a patient s own immune system to fight cancer.

Unlike autologous or personalized therapeutic vaccine approaches which require extraction and processing of cancer or blood from each individual patient, our *ImPACT* therapeutic vaccine uses a master cell line containing a host of known and unknown tumor associated antigens to mass-produce a single vaccine product applicable to all patients with a particular cancer type. We believe our off-the-shelf, allogeneic immunotherapy offers logistical, manufacturing and cost benefits compared to autologous patient-specific approaches.

We commenced active operations in the second half of 2008. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical studies of our most advanced product candidates. To date, we have not generated any revenues and have financed our operations with net proceeds from the private placement of our preferred stock and our initial public offering in which to date we have received gross proceeds of $26 million. As of June 30, 2013, we had a deficit accumulated during the development stage of $8,319,912. We had net losses of $2,462,676 and $1,115,907 for the six months ended June 30, 2013 and 2012, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our

research and development programs or any future commercialization efforts. We expect our existing cash will enable us to fund our current operating plan and capital expenditure requirements for at least 18 months. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so.

RECENT DEVELOPMENTS

On July 29, 2013, we sold 2,500,000 shares of common stock at a public offering price of $10.00 per share and completed our initial public offering (IPO) with estimated net proceeds of $22.1 million (gross proceeds of $25,000,000). On August 15, 2013, we sold an additional 100,000 shares of common stock at a public offering price of $10.00 per share pursuant to the partial exercise of the over-allotment option granted to the underwriters resulting in additional gross proceeds to the Company of $1,000,000. The total gross proceeds raised from the offering and over-allotment option was $26,000,000, before underwriting discounts and commissions and other offering expenses payable by the Company with estimated net proceeds of $23 million. Upon the closing of the IPO, all shares of our then-outstanding preferred stock automatically converted into an aggregate of 1,696,683 shares of common stock. In addition, upon the closing of the IPO, we issued an additional 36,167 shares of our common stock to the Series B Preferred Stockholders and our obligation to issue, and the Series B Preferred Stockholders, obligation to purchase, Series B-2 Preferred Stock under the Stock Purchase Agreement terminated.

On August 27, 2013 we repaid the entire outstanding balance owed to Square 1 Bank in the amount of $725,000 and the loan agreement with Square 1 Bank was terminated.

On September 3, 2013, the Company received written notification from the underwriters of their partial exercise of the over-allotment option to purchase an additional 100,000 shares of the Company s common stock, at a price to the public of $10.00 per share. The closing is scheduled to occur on September 6, 2013.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates which also would have been reasonable could have been used, which would have resulted in different financial results.

Our management s discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our audited condensed consolidated financial statements, which are included in our Prospectus, contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

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Revenue recognition;

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Stock-based compensation;

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Preferred stock warrants liability; and

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Beneficial Conversion Feature.

The Company has elected to follow the extended transition period guidance provided for in Securities Act Section 7(a)(2)(B) for complying with new or revised accounting standards. The Company will disclose the date on which adoption of such standards is required for non-emerging growth companies and the date on which the Company will adopt the recently issued accounting standards.

RESULTS OF OPERATIONS

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

Research and development expense. Research and development expense for the three months ended June 30, 2013 (2013 Quarter) was $688,979 compared to $178,410 for the three months ended June 30, 2012 (2012 Quarter). The $510,569 increase from the 2012 Quarter to the 2013 Quarter is primarily related to an increase of $494,685 in manufacturing costs due to the outsourcing of the vaccine manufacturing from the University of Miami (the University) to an outside vendor and increased consulting fees.

Clinical and regulatory expense. Clinical and regulatory for the 2013 Quarter was $454,934 compared to $100,312 for the 2012 Quarter. The $354,622 increase from the 2012 Quarter to the 2013 Quarter principally resulted from an increase in manufacturing costs of $184,887, consisting primarily of $113,186 and $56,549 of personnel and other costs related to the implementation of our clinical trials.

General and administrative expense. General and administrative expense for the 2013 Quarter was $438,180 compared to $360,394 for the 2012 Quarter. The $77,786 increase from the 2012 Quarter to the 2013 Quarter principally resulted from an increase of $59,926 for personnel costs attributable to the hiring of a Director of Finance and Chief Financial Officer, accrual of Chief Executive Officer s bonus of $18,750, accrued vacation and $52,799 in marketing fees primarily related to preparation for the IPO. Also attributable to the increase were general and administrative costs such as rent, office expenses, fees, insurance and other additional costs associated with growth of the Company of $27,219. These increases were offset by a reduction in professional fees of $41,714 principally attributable to the decrease in accounting fees resulting from the retention of the Director of Finance. There was also a reduction of travel expense of $13,667 and consulting fees of $25,527.

Interest expense. Interest expense increased to $31,799 for the 2013 Quarter from $13,856 for the 2012 Quarter due to increased borrowings.

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

Research and development expense. Research and development expense for the six months ended June 30, 2013 (2013 Period) was $1,129,268 compared to $349,175 for the six months ended June 30, 2012 (2012 Period). The $780,093 increase from the 2012 Period to the 2013 Period is primarily related to an increase of $782,966 in manufacturing costs due to the outsourcing of the vaccine manufacturing from the University to an outside vendor as well as an increase in lab supplies of $44,617 for additional research projects. These increases were offset by a decrease in patent expenditures of $38,542 and $8,948 in other miscellaneous research expenses.

Clinical and regulatory expense. Clinical and regulatory expense for the 2013 Period was $516,991 compared to $147,119 for the 2012 Period. The $369,872 increase from the 2012 Period to the 2013 Period principally resulted from an increase of $191,012 in manufacturing costs for the vaccines, $138,977 in consulting fees and personnel costs and $39,883 in other costs related to implementation of clinical trials.

General and administrative expense. General and administrative expense for the 2013 Period was $706,316 compared to $586,451 for the 2012 Period. The $119,865 increase from the 2012 Period to the 2013 Period principally resulted from an increase of $37,189 for personnel costs, primarily attributable to the hiring of a Director of Finance and Chief Financial Officer, increase in the accrual for the Chief Executive Officer s bonus of $35,417, accrual of vacation pay, an increase of $8,200 in office expense, an increase of $9,444 in insurance costs and an increase in marketing costs of $55,399 primarily in preparation for the IPO offset by a $23,419 decrease in travel costs and $2,365 in other miscellaneous expenses.

Interest expense. Interest expense increased to $60,141 for the 2013 Period from $15,615 for the 2012 Period due to increased borrowings.

Balance Sheet at June 30, 2013 and December 31, 2012

Prepaid expenses. Prepaid expenses was $500,376 as of June 30, 2013 compared to $58,436 as of December 31, 2012. The increase of $441,940 was primarily due to $351,605 of outside services related to our Initial Public

Offering. These costs are capitalized until the consummation of the offering at which time they will be reclassified to additional paid in capital. Additionally there was a deposit to a vendor of $90,335 for future services. These additional costs were offset by amortization of other prepaids such as insurance.

Accounts Payable. Accounts payable was $1,319,036 as of June 30, 2013 compared to $505,471 as of December 31, 2012. This increase of $813,565 was primarily related to the reclassification of the convertible note plus accrued interest totaling $497,380 to accounts payable upon agreement with the vendor. The residual increase of $316,185 was principally due to increased manufacturing costs for both clinical and regulatory and research and development.

Convertible note payable. Convertible note payable was $0 as of June 30, 2013 compared to $197,099 as of December 31, 2012. This decrease was due to the reclassification of the entire balance of $197,099 to accounts payable during the 2013 Period.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

To date, we have not generated any revenues. Since our inception in June, 2008, we have financed our operations principally through private placements and through our initial public offering, which we closed in July, 2013 and the closing of the partial exercise of the underwriter s over-allotment option. The total gross proceeds raised from the offering and over-allotment option was $26,000,000, before underwriting discounts and commissions and other offering expenses payable by the Company for estimated net proceeds of $23 million. We believe that the proceeds we received from the sale of the shares in our initial public offering will provide us with sufficient working capital to fund our Phase 2 clinical trial for non-small cell lung cancer and our Phase 1/2 clinical trial for bladder cancer. Thereafter, we expect to require additional funds in the future to conduct additional clinical trials. As of June 30, 2013, we had $3,015,738 in cash. As of August 30, 2013, our cash balance was approximately $24.9 million.

Our cash is currently held in an interest bearing checking and money market account.

Cash flows

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and favorable changes in the components of working capital. The significant increase in cash used in operating activities for the 2013 Period compared to the 2012 Period is due to an increase in research and development expenses as we increased manufacturing costs for both research and development and clinical and regulatory as we approached the target date for the initiation of our clinical trials.

Financing activities. Cash provided by financing activities during the 2013 Period of approximately $4.9 million resulted primarily from the issuance of $5.1 million of Series B-1 preferred stock during the 2013 Period, less $145,510 of stock issuance costs.

Funding requirements

We expect our existing cash will enable us to fund our current operating plan and capital expenditure requirements for at least the next 18 months.

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 Securities and Exchange Commission rules.

SUBSEQUENT EVENTS

On September 4, 2013, we severed our relationship with Jennifer Harris, a part-time employee who served as our Vice President of Clinical and Regulatory Affairs. We have made an offer to an individual to serve as our full-time Vice President of Clinical and Regulatory Affairs and expect to finalize negotiations with such individual in the next few weeks.

ITEM 3.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable to smaller reporting companies.

ITEM 4.

CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2013, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses discussed in ITEM 1A. Risk Factors.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended June 30, 2013 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1.

LEGAL PROCEEDINGS.

None.

ITEM 1A.

RISK FACTORS.

Investors should carefully consider the risks described below before deciding whether to invest in our securities. If any of the following risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this Quarterly Report on Form 10-Q as a result of different factors, including the risks we face described below.

Risks Relating to our Company

We have had limited operations to date.

We are a start-up entity and have had limited operations to date. As a start-up entity, we are subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and products, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. Even if we generate revenue, there can be no assurance that we will be profitable. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks.

We have a limited operating history upon which to evaluate our ability to commercialize our products.

We are a development-stage company and our success is dependent upon our ability to obtain regulatory approval for and commercialize our products and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

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continuing to undertake pre-clinical development and initiate clinical trials;

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participating in regulatory approval processes;

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formulating and manufacturing products; and

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conducting sales and marketing activities.

While various members of our management and staff have significant experience in conducting cancer trials, the Company, to date, has not successfully initiated any clinical trials and has no experience conducting or enrolling patients in clinical trials. Our operations have been limited to organizing and staffing the Company, acquiring, developing and securing our proprietary technology and undertaking pre-clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We currently have no product revenues and may not generate revenue at any time in the near future, if at all.

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot commercialize our product candidates and will not have product revenues. For the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand, grants, and, potentially, future offerings. We believe we have sufficient cash on hand to fund our Phase 2 clinical trial for NSCLC, and our Phase 1/2 clinical trial for bladder cancer. However, changes may occur that would consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, pre-clinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results.

We may continue to generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.

For the six months ended June 30, 2013 and June 30, 2012, we incurred a net loss attributable to common stockholders of ($4,684,630) and ($1,101,529), respectively. For the years ended December 31, 2012 and December 31, 2011, we incurred a net loss of ($2,420,200) and ($2,104,884), respectively. We have also incurred a deficit accumulated during the development stage of ($8,319,912). We may continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on the market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

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continue to undertake pre-clinical development and initiate clinical trials for product candidates;

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seek regulatory approvals for product candidates;

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implement additional internal systems and infrastructure; and

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hire additional personnel.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would likely negatively impact the value of our securities and could prevent us from continuing as a going concern.

Risks Relating to our Business

If we do not obtain the necessary regulatory approvals in the U.S. and/or other countries we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a Biologics License Application, or BLA, demonstrating that the product candidate is safe, pure and potent, or effective for its intended use. This demonstration requires significant research including pre-clinical studies, as well as clinical trials. Satisfaction of the FDA s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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prevent or delay commercialization of, and our ability to derive product revenues from, our product candidates; and

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diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. Regulatory approval of oncology

products often requires that patients in clinical trials be followed for long periods to assess their overall survival. The results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA s exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any vaccines. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

Our product candidates are in early stages of development.

Because our product candidates are in early stages of development they will require extensive pre-clinical and clinical testing. Only one product candidate is currently ready for Phase 2 clinical trials. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. For example, the only clinical study conducted to date with one of our product candidates by the inventor of the technology that we license showed evidence of an immune response in late-stage NSCLC patients exposed to HS-110. However, our future HS-110 trials will use doses and dosing regimens which have previously been tested in only 0 to 3 subjects, and will be conducted in patients with less advanced disease who may have different responses. In addition, immune response is not an acceptable regulatory endpoint for approval, and no actual clinical or tumor responses were observed in that study. Moreover, the HS-110 Phase 1 trial involved a small sample size, was not blinded and was sponsored by an individual who has a significant financial interest in the success of the product candidate. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

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. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

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unforeseen safety issues;

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failure to determine appropriate dosing;

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greater than anticipated cost of our clinical trials;

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failure to demonstrate effectiveness during clinical trials;

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slower than expected rates of patient recruitment or difficulty obtaining investigators;

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patient drop-out or discontinuation;

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inability to monitor patients adequately during or after treatment;

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third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

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insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;

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potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;

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problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;

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imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and

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inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed. We intend to submit the protocol for our planned Phase 2 trial of HS-110 to the FDA in 2H-2013.

There is uncertainty as to market acceptance of our technology and product candidates.

Even if the FDA approves one or more of our product candidates, the products may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates; however we cannot guarantee market acceptance of our product candidates, if approved, and have somewhat limited information on which to estimate our anticipated level of sales. Our product candidates, if approved, will require patients, healthcare providers and doctors to adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers the demand for our products will be reduced. Acceptance and use of any products we market will depend upon a number of factors including:

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perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;

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limitation on use or warnings required by FDA in our product labeling;

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cost-effectiveness of our products relative to competing products;

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convenience and ease of administration;

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potential advantages of alternative treatment methods;

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availability of reimbursement for our products from government or other healthcare payers; and

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effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of our current product candidates, if approved, the failure of these therapeutics to find market acceptance would substantially harm our business and would adversely affect our revenue.

Our development program depends upon third-party researchers who are outside our control.

We are dependent upon independent investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new product candidates, if any, will be delayed if obtained at all. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

To date, in excess of $14,000,000 of funding has been awarded by the NIH to the primary inventor of the technology we license. We have little control over the direction of the NIH grant funds that have been received by the primary inventor of the technology we license and since payment is made to the inventor as opposed to us, we do not recognize any revenue from such grant funds nor do they fund any expenses that we incur.

Although earmarked for further development of the technology that we license, any funds awarded to the primary inventor are used in his discretion and we have little control over his use of the funds.

We will rely exclusively on third parties to formulate and manufacture our product candidates.

We have no experience in the formulation, development or manufacturing of biologics and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational product for our planned Phase 1 and Phase 2 clinical trials are manufactured by our contractors under current good manufacturing practices, or cGMPs and we have entered into an agreement with another manufacturer for the manufacture and supply of investigational product for additional Phase 2 and any Phase 3 clinical trials and commercialization efforts We must also develop and validate a potency assay prior to submission of a license application. Such assays have proven difficult to develop for cell-based products and must be established prior to initiating any Phase 3 clinical trials. While we are currently utilizing gp96 ELISA as our potency assay, this is unlikely to be adequate for licensure, and as necessary, we will rely on contract manufacturers for further development and validation of a potency assay which will support our license application. If any of our current product candidates or any product candidates we may develop or acquire in the future receive FDA approval, we will rely on one or more third-party contractors for manufacturing. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers with appropriate expertise and facilities is limited.

If we change manufacturers at any point during the development process or after approval, if any, we will need to demonstrate comparability between the products made by the old and new manufacturers. If we are unable to do so, we may need to conduct additional clinical trials with product manufactured by the new manufacturer. For example, the manufacturer of the clinical trial material we intend to use for any future Phase 3 trials of HS-110 and of our commercial product, if approved, is a different manufacturer from the manufacturer of the inventor s completed Phase 1 trial of HS-110 and portions of our planned initial Phase 2 trial of HS-110. Accordingly, the third stage of our planned Phase 2 trial of HS-110 will evaluate the comparability of HS-110 produced by the two different manufacturers.

If we change the manufacturer of a product subsequent to the approval of the product, we will need to obtain approval from the FDA of the change in manufacturer. Any such approval would require significant testing and expense, and the new manufacturer may be subject to a cGMP inspection prior to approval.

Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and with the quality required to meet our clinical needs and commercial needs, if any.

Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies to ensure compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to assess compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we or our contract manufacturers are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

Even if we are able to obtain regulatory approval for our product candidates, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure, or the failure of our contract manufacturers, to comply with these requirements could substantially harm our business.

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record-keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls or seizures. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

We have no experience selling, marketing or distributing products and have no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator s strategic interest in the products under development and such collaborator s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our

products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

We may seek to enter into strategic partnerships in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our products. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or return on investment. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If we ultimately determine that entering into strategic partnerships is in our best interest but either fail to enter into, are delayed in entering into or fail to maintain such strategic partnerships:

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the development of certain of our current or future product candidates may be terminated or delayed;

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our cash expenditures related to development of certain of our current or future product candidates may increase significantly and we may need to seek additional financing;

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we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;

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we will bear all of the risk related to the development of any such product candidates;

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the competitiveness of any product candidate that is commercialized could be reduced.

To the extent we elect to enter into licensing or collaboration agreements to partner our product candidates, our dependence on such relationships may adversely affect our business.

Our commercialization strategy for certain of our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements, and our product candidates subject to collaborative arrangements may never be successfully developed or commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or fewer resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If any of our product candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have oncology compounds already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

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developing drugs, biologics and other therapies;

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undertaking pre-clinical testing and clinical trials;

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obtaining FDA and other regulatory approvals of drugs, biologics and other therapies;

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formulating and manufacturing drugs, biologics and other therapies; and

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launching, marketing and selling drugs, biologics and other therapies.

We have limited protection of our intellectual property.

We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have obtained exclusive rights to license the technology for which patent protection has been obtained; however such protection does not prevent unauthorized use of such technology. Trademark and copyright protections may be limited, and enforcement could be too costly to be effective. It may also be possible for unauthorized third parties to copy aspects of, or otherwise obtain and use, our proprietary information without authorization, including, but not limited to, product design, software, customer and prospective customer lists, trade secrets, copyrights, patents and other proprietary rights and materials. Other parties can use and register confusingly similar business, product and service names, as well as domain names, which could divert customers, resulting in a material adverse effect on our business, operating results and financial condition.

If we fail to successfully enforce our intellectual property rights, our competitive position could suffer, which could harm our operating results. Competitors may challenge the validity or scope of our patents or future patents we may obtain. In addition, our licensed patents may not provide us a meaningful competitive advantage. We may be required to spend significant resources to monitor and police our licensed intellectual property rights. We may not be able to detect infringement and our competitive position may be harmed. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture market share.

The technology we license, our products or our development efforts may be found to infringe third-party intellectual property rights.

Third parties may in the future assert claims or initiate litigation related to their patent, copyright, trademark and other intellectual property rights in technology that is important to us. The asserted claims and/or litigation could include claims against us, our licensors or our suppliers alleging infringement of intellectual property rights with respect to our products or components of those products. Regardless of the merit of the claims, they could be time consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non-infringing technology or enter into license agreements. We have not undertaken an exhaustive search to discover any third party intellectual patent rights which might be infringed by commercialization of the product candidates described herein. Although we are not currently aware of any such third party intellectual patent rights, it is possible that such rights currently exist or might be obtained in the future. In the event that a third party controls such rights and we are unable to obtain a license to such rights on commercially reasonable terms, we may not be able to sell or continue to develop our products, and may be liable for damages for such infringement. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

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obtain licenses, which may not be available on commercially reasonable terms, if at all;

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abandon an infringing drug or therapy candidate;

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redesign our products or processes to avoid infringement;

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stop using the subject matter claimed in the patents held by others;

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pay damages; or

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defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We rely on licenses to use various technologies that are material to our business and if the agreements were to be terminated or if other rights which may be necessary or we deem advisable for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

We have licensing agreements with certain universities granting us the right to use certain critical intellectual property. The terms of the licensing agreements continues until the end of the life of the last patent to expire. If we breach the terms of these licensing agreements, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones, using best efforts to introduce a licensed product in certain territories by 2020, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain these licenses on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

We may be unable to generate sufficient revenues to meet the minimum royalties or developmental milestones required under our license agreements.

For the years ended December 31, 2013, 2014, 2015, 2016, 2017 and thereafter through December 31, 2022 our minimum royalty obligations under our licensing agreements, required to be paid with the passage of time, are $30,000, $30,000, $30,000, $30,000, $280,000 and $150,000, respectively. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments. The license agreements also provide for certain developmental milestones. No assurance can be given that we will meet all of the required developmental milestones. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

Our ability to generate product revenues will be diminished if our therapies sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our vaccines, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

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government and health administration authorities;

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private health maintenance organizations and health insurers; and

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other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and therapeutics. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payers

satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such vaccines. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced.

Legislative and regulatory changes affecting the health care industry could adversely affect our business.

Political, economic and regulatory influences are subjecting the health care industry to potential fundamental changes that could substantially affect our results of operations. U.S. and foreign governments, for example, continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, the government controls the pricing and profitability of prescription pharmaceuticals. In the U.S., we expect that there will continue to be federal and state proposals to implement similar governmental controls. In addition, recent changes in the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payers for health care treatment and services may take in response to any health care reform proposal or legislation. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainly remains regarding proposed significant reforms to the U.S. health care system.

We may not successfully effect our intended expansion.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We may be exposed to liability claims associated with the use of biological and hazardous materials and chemicals.

Our research and development activities may involve the controlled use of biological and hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. Other than a $2,000,000 insurance policy on the life of Jeffrey Wolf, we do not have key person life insurance policies for any of our officers or advisors. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in pre-clinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. In particular, over the next 12 months, we expect to hire up to 10 new employees. We compete for qualified individuals with numerous

biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Certain of our officers may have a conflict of interest.

Some of our officers are currently working for the Company on a part-time basis. Several of the part-time employees also work at other jobs and have discretion to decide what time they devote to our activities, which may result in a lack of availability when needed due to responsibilities at other jobs. We expect that some of these officers may join the Company on a full-time basis, but there can be no assurance given that any or all of our officers will be so employed.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of drug and biological product candidates entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. Clinical trial liability claims may be filed against us for damages suffered by clinical trial subjects or their families. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products which could impact our ability to continue as a going concern. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. In addition, regardless of merit or eventual outcome, product liability claims may result in:

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decreased demand for any approved product candidates;

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impairment of our business reputation;

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withdrawal of clinical trial participants;

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costs of related litigation;

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distraction of management s attention;

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substantial monetary awards to patients or other claimants;

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loss of revenues; and

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the inability to successfully commercialize any approved drug candidates.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy incorporates international expansion, including establishing and maintaining clinician marketing and education capabilities outside of the United States and expanding our relationships with distributors and manufacturers. Doing business internationally involves a number of risks, including:

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multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

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failure by us or our distributors to obtain regulatory approvals for the sale or use of our product candidates in various countries;

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difficulties in managing foreign operations;

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complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;·

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limits on our ability to penetrate international markets if our product candidates cannot be processed by a manufacturer appropriately qualified in such markets;

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financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;·

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reduced protection for intellectual property rights;

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natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

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failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve or continues to deteriorate, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

The U.S. government may have march-in rights to certain of our intellectual property.

Because federal grant monies were used in support of the research and development activities that resulted in certain of our issued pending U.S. patent applications, the federal government retains what are referred to as march-in rights to patents that are granted on these applications.

In particular, the National Institutes of Health, which administered grant monies to the primary inventor of the technology we license, technically retain the right to require us, under certain specific circumstances, to grant the U.S. government either a nonexclusive, partially exclusive or exclusive license to the patented invention in any field of use, upon terms that are reasonable for a particular situation. Circumstances that trigger march-in rights include, for example, failure to take, within a reasonable time, effective steps to achieve practical application of the invention in a field of use, failure to satisfy the health and safety needs of the public and failure to meet requirements of public use specified by federal regulations. The National Institutes of Health can elect to exercise these march-in rights on their own initiative or at the request of a third-party.

Risks Related to Our Common Stock

Certain of our officers and directors have sufficient voting power to make corporate governance decisions that could have a significant effect on us and the other stockholders.

As of August 30, 2013 our officers and directors together beneficially own approximately 36.13% of our outstanding common stock on a fully diluted basis. Mr. Wolf alone through his direct and indirect holdings beneficially owns approximately 21.4% of our outstanding common stock on a fully diluted basis. As a result, Mr. Wolf, alone 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 directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in our control and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that we would not otherwise consider.

The possible issuance of common stock subject to options and warrants may dilute the interest of stockholders.

In 2009, we adopted a 2009 Stock Option and Restricted Stock Plan under which we may grant awards to purchase 869,565 shares of our common stock, of which, 644,280 options were outstanding as of June 30, 2013. In addition, as of June 30, 2013, we have 53,159 shares issuable upon exercise of warrants granted to third parties in connection with prior private placements of our equity securities and debt which excludes 125,000 shares of common stock issuable at $12.50 per share upon exercise of warrants issued to the underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our common stock.

Our Third Amended and Restated Certificate of Incorporation authorizes the issuance of 50,000,000 shares of our common stock and 10,000,000 shares of Preferred Stock. The common stock and preferred stock, as well as the awards available for issuance under the 2009 Stock Option and Restricted Stock Plan, can be issued by our board of

directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of Preferred Stock and common stock. In addition, the issuance of Preferred Stock may be used as an anti-takeover device without further action on the part of our stockholders, and may adversely affect the holders of the common stock.

We have never paid dividends and have no plans to pay dividends in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our shares of our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

We are an emerging growth company, and any decision on our part to comply with certain reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act enacted in April 2012, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board, or the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to shareholders of such companies.

Under Section 107(b) of the Jumpstart Our Business Startups Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

As a result of being a public company, we are subject to additional reporting and corporate governance requirements that will require additional management time, resources and expense.

As a public company we are obligated to file with the U.S. Securities and Exchange Commission annual and quarterly information and other reports that are specified in the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. We are also subject to other reporting and corporate governance requirements under the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated thereunder, all of which impose significant compliance and reporting obligations upon us and require us to incur additional expense in order to fulfill such obligations.

We have identified material weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results, prevent fraud, or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Prior to the closing of our initial public offering in July 2013, we operated as a private company and the number and qualifications of our finance and accounting staff have not been consistent with those of a public company. We have identified material weaknesses in our internal controls with respect to our financial statement closing process of our condensed consolidated financial statements for the years ended December 31, 2012 and 2011. Our management discovered certain conditions that we deemed to be material weaknesses and significant deficiencies in our internal controls, as follows:

A lack of accounting and finance resources as well as effective oversight by those in charge of governance resulted in insufficient controls over timely financial statement preparation and review as well as the preparation and review around accounting for certain complex transactions.

The design of monitoring controls used to assess the design and operating effectiveness of our internal controls is inadequate. We also do not have an adequate internal process to report deficiencies in internal control to management on a timely basis.

We have begun to take actions that we believe will substantially remediate the material weaknesses identified. In response to the identification of our material weaknesses, we: (i) have retained a part-time Chief Financial Officer to segregate the duties of Chief Executive Officer and Chief Financial Officer; (ii) are in the process of establishing a review process for key aspects of our financial reporting process, including the accounting for complex transactions; and (iii) will seek to establish better operating controls and involve our board of directors in our internal controls process, which will involve establishing formal procedures to communicate deficiencies in internal controls on a timely basis, and encourage our board of directors to more actively participate in guiding management as it relates to internal controls matters. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our finance and accounting staff.

Future sales of our common stock by our existing shareholders could cause our stock price to decline.

We have a significant number of restricted shares that will become eligible for sale at the end of January 2014. We currently have 6,194,719 shares of our common stock outstanding, of which 2,600,000 shares sold in our initial public offering including the 100,000 shares issued upon partial exercise of the underwriter s over-allotment option) are currently eligible for sale in the public market. All of the remaining shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the effective date of our registration statement on Form S-1, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 or 701 promulgated under the Securities Act. It is conceivable that following the holding period, many shareholders may wish to sell some or all of their shares. If our shareholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our shareholders might sell significant shares of our common stock could also depress the market price of our common stock.

A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause shareholders to lose part or all of

their investment in our shares of common stock.

Our shares of common stock are from time to time thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been thinly-traded, meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution.

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We believe that the proceeds we received from the sale of the shares in our initial public offering will provide us with sufficient working capital to fund our Phase 2 clinical trial for Non-Small Cell Lung Cancer and our Phase 1/2 clinical trial for bladder cancer. Thereafter, we expect to require additional funds in the future to conduct additional clinical trials. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current shareholders, or upon terms which may be deemed more favorable than those offered to current shareholders. In addition, the issuance of securities in any future financing may dilute an investor's equity ownership. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

Certain provisions of the General Corporation Law of the State of Delaware may have anti-takeover effects which may make an acquisition of our company by another company more difficult.

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination, including mergers and asset sales, with an interested stockholder (generally, a 15% or greater stockholder) 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 operation of Section 203 may have anti-takeover effects, which could delay, defer or prevent a takeover attempt that a holder of our common stock might consider in its best interest.

ITEM 2.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

RECENT SALES OF UNREGISTERED SECURITIES

Set forth below is information regarding securities sold by us during the six months ended June 30, 2013, that were not registered under the Securities Act of 1933, as amended, or the Securities Act. Also included is the consideration, if any, received by us for the securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

Issuances of securities

Upon the closing of the IPO in July 2013, all shares of our then-outstanding preferred stock automatically converted into an aggregate of 1,696,683 shares of common stock. The issuance qualified for exemption under Section 3(a)(9) of the Securities Act. In July 2013 in connection with the IPO we issued an additional 36,167 shares of our common stock to the Series B Preferred Stockholders and our obligation to issue and their obligation to purchase, Series B-2 Preferred Stock, under the Stock Purchase Agreement we entered into with them was terminated.

In April and May 2013, we issued options exercisable for an aggregate of 72,496 shares of common stock at an exercise price of $8.81 to 8 individuals for services rendered.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

Use of Proceeds

In connection with our IPO, in July and August of, 2013, we offered and sold an aggregate of 2,600,000 shares of common stock (including the 100,000 shares issued pursuant to the over- allotment option) at a price of $10.00 per share. The offer and sale of the shares in the initial public offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 effective on July 23, 2013 (file number 333-188365). Aegis Capital Corp was the sole book-running manager in the offering and Cantor Fitzgerald & Co. was the co-manager. Aggregate gross proceeds from the IPO, including the exercise of the over-allotment option with respect to 100,000 shares of common stock, were $26,000,000 and estimated net proceeds received after underwriting commissions and offering expenses of $3 million were approximately $23 million. Until September 6, 2013 the underwriters have the right to acquire an additional 275,000 shares of common stock pursuant to the over-allotment option. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours.

Because the closing of the IPO occurred on July 29, 2013 and the over-allotment option closing occurred on August 15, 2013, as of June 30, 2013, we had not received the net proceeds from the sale of these securities and therefore had used none of the proceeds to fund operations, capital expenditures, working capital and other general corporate purposes as of such date. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in the prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act other than the repayment in full of the amount outstanding to Square 1 Bank.

PURCHASE OF EQUITY SECURITIES

None.

ITEM 5.

OTHER INFORMATION.

None.

ITEM 6.

EXHIBITS.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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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.

HEAT BIOLOGICS, INC.

Date: September 5, 2013	By:	/s/ JEFFREY A. WOLF Jeffrey A. Wolf *Chairman and Chief Executive Officer* *(Principal executive officer)*
Date: September 5, 2013	By:	/s/ MATTHEW E. CZAJKOWSKI Matthew E. Czajkowski *Chief Financial Officer* *(Principal financial and accounting officer)*

EXHIBIT INDEX

Exhibit No.	Description
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*

Filed herewith.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.