

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Amendment No. 4 to  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**Heat Biologics, Inc.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**541700**

*(Primary Standard Industrial  
Classification Code Number)*

**26-2844103**

*(I.R.S. Employer  
Identification Number)*

**100 Europa Drive  
Chapel Hill, North Carolina 27517  
(919) 240-7133**

*(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)*

**Jeffrey Wolf  
Chief Executive Officer and  
Chairman of the Board of Directors  
Heat Biologics, Inc.  
100 Europa Drive  
Chapel Hill, North Carolina 27517  
(919) 240-7133**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

**Copies to:**

**Hank Gracin, Esq.  
Leslie Marlow, Esq.  
Gracin & Marlow, LLP  
The Chrysler Building  
405 Lexington Avenue, 26<sup>th</sup> Floor  
New York, New York 10174  
(212) 907-6457**

**Yvan-Claude Pierre, Esq.  
Daniel I. Goldberg, Esq.  
Reed Smith LLP  
599 Lexington Avenue  
New York, New York 10022  
(212) 521-5400**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 424, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)	Amount of registration fee(2)
Common Stock, \$0.0002 par value (2)(3)	31,363,632	4,278
Representative's Warrants(4)	—	—
Shares of Common Stock underlying Representative's Warrants (2)(5)	1,704,545	233
<b>Total</b>	<b>33,068,177</b>	<b>4,511 (6)</b>

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) of the Securities Act of 1933, as amended.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Includes shares of common stock the underwriters have the option to purchase to cover over-allotments, if any.

(4) No fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended. The representative's warrants are exercisable at a per share exercise price equal to 125% of the public offering price per share. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act of 1933, as amended, the proposed maximum aggregate offering price of the representative's warrants is \$1,704,545 which is equal to 125% of \$1,363,636 (5% of \$27,272,724).

(6) \$3,275 was previously paid.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED JULY 8, 2013

## 2,272,727 Shares Common Stock



This is a firm commitment initial public offering of 2,272,727 shares of common stock by Heat Biologics, Inc. No public market currently exists for our shares. We anticipate that the initial public offering price per share of our shares of common stock will be between \$10.00 and \$12.00 per share.

We effected a 1-for-2.3 reverse stock split of our outstanding common stock on May 29, 2013. Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol "HTBX."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

**Investing in our common stock involves risk. See "Risk Factors" beginning on page 9 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Public offering price	\$	\$
Discounts and commissions to underwriters (1)	\$	\$
Offering proceeds to us, before expenses	\$	\$

(1) Does not include a non-accountable expense allowance equal to 1% of the gross proceeds of this offering payable to Aegis Capital Corp., the representative of the underwriters. See "Underwriting" beginning on page 102 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to 340,909 additional shares of common stock solely to cover over-allotments, if any.

The underwriters expect to deliver our shares to purchasers in the offering on or about \_\_\_\_\_, 2013.

*Sole Book-Running Manager*

**Aegis Capital Corp**

*Co-Manager*

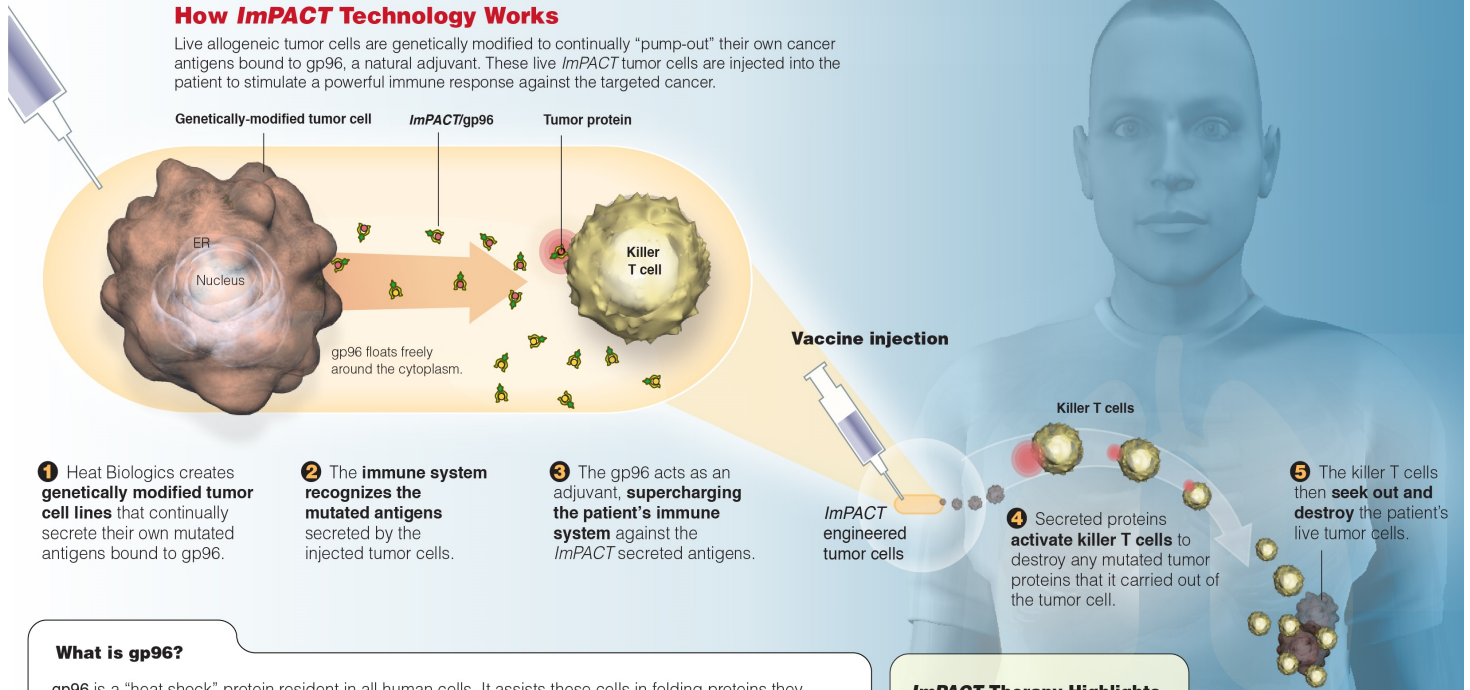
**Cantor Fitzgerald & Co.**

, 2013

Heat Biologics' proprietary **Immune Pan Antigen Cytotoxic Therapy (ImPACT)** reprograms live "allogeneic" cancer cells to continually secrete their own antigens bound to heat shock protein gp96 to seek out and destroy a variety of tumors.

### How ImPACT Technology Works

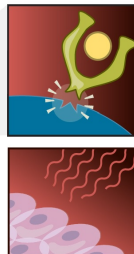
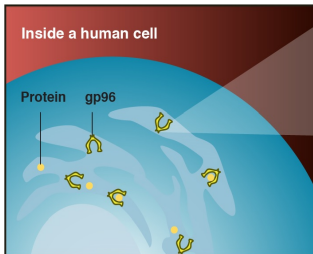
Live allogeneic tumor cells are genetically modified to continually "pump-out" their own cancer antigens bound to gp96, a natural adjuvant. These live *ImPACT* tumor cells are injected into the patient to stimulate a powerful immune response against the targeted cancer.



- 1 Heat Biologics creates **genetically modified tumor cell lines** that continually secrete their own mutated antigens bound to gp96.
- 2 The **immune system recognizes the mutated antigens** secreted by the injected tumor cells.
- 3 The gp96 acts as an adjuvant, **supercharging the patient's immune system** against the *ImPACT* secreted antigens.

#### What is gp96?

gp96 is a "heat shock" protein resident in all human cells. It assists these cells in folding proteins they produce. gp96 is tethered to the cell and is normally only released during "necrosis", or unnatural cell death.



#### What is ImPACT Technology?

Heat Biologics "severs the leash" that binds gp96 to the cell, thus creating modified living cells that continually secrete gp96 bound to the proteins produced by the cell.

These modified tumor cells are then mass-produced and irradiated to prevent them from replicating when injected into the patient.

#### ImPACT Therapy Highlights

- Initiates a pan-antigen cytotoxic T-cell attack against the targeted cancer
- Generates a significant adjuvant response
- Targets a wide variety of cancers

*ImPACT* is an allogeneic, "off-the-shelf" cancer therapy. In contrast to other "autologous" cancer therapies, no invasive procedure to remove patient tumor or immune cells is required.

Some killer T cells become long-living memory cells used to fight metastatic and recurrent cancers.

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You should rely only on the information contained in this prospectus. Neither we nor the underwriters have authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.

Except where the context requires otherwise, in this prospectus the “Company,” “Heat Biologics,” “Heat,” “we,” “us” and “our” refer to Heat Biologics, Inc., a Delaware corporation formed in June 2008, and, where appropriate, its subsidiaries, Heat Biologics I, Inc., Heat Biologics III, Inc., Heat Biologics IV, Inc. and Heat Biologics GmbH. In June 2012, we divested our 92.5% interest in Heat Biologics II, Inc. The divestiture resulted in Heat Biologics II, Inc. being classified as discontinued operations in our consolidated financial statements for the years ended December 31, 2012 and 2011 and for the three months ended March 31, 2012 (unaudited), and for the period June 10, 2008 (inception) through March 31, 2013 (unaudited).

For investors outside the United States: Neither we nor any of the underwriters have taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of shares of common stock and the distribution of this prospectus outside of the United States.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding to invest in our securities. We urge you to read this entire prospectus carefully, especially the "Risk Factors" section. Except where the context requires otherwise, in this prospectus the "Company," "Heat Biologics," "Heat," "we," "us" and "our" refer to Heat Biologics, Inc., a Delaware corporation, and, where appropriate, its subsidiaries, Heat Biologics I, Inc. Heat Biologics III, Inc., Heat Biologics IV, Inc. and Heat Biologics GmbH. Unless otherwise included, all share amounts and per share amounts in this prospectus have been presented on a pro forma basis to reflect the reverse stock split of our outstanding shares of common stock at a ratio of 1-for-2.3, that we effected on May 29, 2013.*

### Heat Biologics

#### 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*<sup>™</sup> 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.

Our primary product candidates are HS-110 and HS-410.

#### HS-110

We have submitted an IND to initiate a Phase 2 clinical trial in non-small cell lung cancer (NSCLC) patients with our therapeutic vaccine candidate HS-110, which is derived from a human lung cancer cell line. HS-110 is a biologic product which consists of a lung cancer cell line that has been genetically modified using our *ImPACT* technology platform to secrete a wide range of lung cancer associated antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient's cancer. The inventor of the *ImPACT* technology that we license recently reported results from a Phase 1 open-label, single center clinical trial of HS-110 in patients with advanced NSCLC. We believe the results provide clinical evidence that HS-110 is capable of generating anti-cancer immune responses. Eighteen patients were vaccinated, and 15 of the 18 vaccinated patients completed the first course of three planned courses of therapy. Two patients completed all three planned courses of therapy.

HS-110 showed no overt toxicity. There were no serious adverse events (SAEs) that were considered by the trial investigator to be treatment-related. Most of the adverse events (AEs) were reported as mild or moderate (grade 1 or 2) with the most frequent being skin induration and rash that were transitory and usually resolved in 1 to 2 weeks. HS-110 provides evidence of a CD8-CTL IFN- $\gamma$  immune response in patients with advanced NSCLC. In 11 of the 15 patients (73%) that completed the first course of therapy with HS-110, there was a twofold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN-  $\gamma$ ). These patients also exhibited an estimated median survival of 16.5 months (95% CI:7.1-20.0). In contrast, 4 patients were immune non-responders and survived 2.1, 2.3, 6.7, and 6.7 months, or a median survival of 4.5 months, which is consistent with the expected survival times in this patient population. The protocol required that we look for such responses, but, as is typical in immunotherapy, no partial or complete tumor responses were observed. The median one-year overall survival rate of patients in the study was 44% (95% CI:21.6-65.1), comparing favorably to a 5.5% rate based on published data from a 43-patient advanced lung cancer population. One of the late-stage lung cancer patients is surviving over four years since starting the therapy and another patient is surviving over three years since starting the therapy. These findings were consistent with multiple pre-clinical published studies on *ImPACT* therapy.

## HS-410

We intend to submit an IND to initiate a Phase 1/2 bladder cancer trial with HS-410, which is derived from a human bladder cancer cell line. HS-410 is a biologic product which consists of a bladder cancer cell line which has been genetically modified using our *ImPACT* technology platform to secrete a wide range of bladder cancer antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient's bladder cancer. Following FDA clearance, we intend to initiate a 93 patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 6 weekly intravesical bacillus Calmet-Guerin (BCG) immunotherapy installations. We anticipate including approximately 8-10 clinical sites with an enrollment period of 12-18 months. Patient enrollment is expected to begin in the third quarter of 2013.

### Additional Indications

We are also developing *ImPACT* therapeutic vaccines for breast cancer and ovarian cancer. The inventor of the *ImPACT* technology intends to initiate a second grant-funded, investigator-sponsored Phase 1/2 clinical trial of *ImPACT* therapy in conjunction with other therapies against NSCLC in the third quarter of 2013. To date, in excess of \$14,000,000 of funding has been awarded to the primary inventor of the technology that we license by the National Institutes of Health (NIH) and through other research and clinical grants, which has been used to further develop the *ImPACT* technology platform. The NIH is also currently fully funding the primary inventor's study of an HS-HIV product candidate in non-human primates with a therapeutic and prophylactic vaccine for the treatment and prevention of HIV utilizing the *ImPACT* approach.

The table below summarizes our current product candidates and their stages of development:

Product Candidate	Indication	Phase of Development	Upcoming Milestone(s)
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Open commercial IND	2013 - Initiate Phase 2
HS-410	Bladder Cancer Adjuvant	IND submission planned. Completing cGMP Drug Manufacturing	2013 - Initiate Phase 1/2
HS-310	Ovarian Cancer	Pre-clinical. Initiating cGMP Drug Manufacturing	2014 - Phase 1/2 trials
HS-510	Triple Negative Breast Cancer (TNBC)	Pre-clinical. Cell line development underway	2014 - Phase 1/2 trials

The table below summarizes the primary inventor's clinical development of the *ImPACT* technology:

Product Candidate	Indication	Phase of Development
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Completed Phase 1 Interim Study Report
HS-110	Non-Small Cell Lung Cancer (NSCLC) Combination Therapy	Completed cGMP Drug Manufacturing. 2013 - Initiate Phase 1/2
HS-HIV	HIV	Pre-clinical. NIH-sponsored Primate Studies Completed

Our intellectual property portfolio consists of 5 patent families representing at least 37 pending applications in the U.S. and worldwide, with enforceable patents in 13 countries. This portfolio includes patents and proprietary rights around (i) our drug candidates and (ii) *ImPACT*-focused intellectual property, which includes early and broad filings on therapeutic vaccines utilizing cells secreting heat shock proteins.



### ***ImPACT* Therapy—Novel Pan-Antigen Immune Activation**

Our *ImPACT* therapy is a novel technology platform designed to educate and stimulate the immune system to combat specific disease targets, such as cancer cells. *ImPACT* utilizes live, human-derived, genetically-modified attenuated cells that generate an array of tumor associated antigens complexed to a secreted immunostimulatory protein called “gp96”, a heat shock protein. The secreted antigen and adjuvant complex are designed to generate a potent immune response to cancer cells by mobilizing and activating a patient’s own killer T cells to recognize and attack a broad array of different tumor antigens with the goal of eliminating cancer cells. In contrast to other vaccine technologies that target only single cancer antigens, *ImPACT*’s pan-antigen approach is designed to enable the patient to induce and maintain an immune response against a broad array of tumor-specific proteins, by potentially providing a more robust immune response and limiting cancer cells’ ability to evade the immune system. We believe that the clinical and pre-clinical results of the trials conducted by the inventor of the technology we license suggest that *ImPACT* generates anti-tumor immune responses. We believe these responses may be capable of targeting tumors and maintaining remission. We plan to study our novel, off-the-shelf, live attenuated cell therapy not only as therapy for a wide range of cancers, but also to treat various infectious diseases, such as hepatitis C, malaria and HIV. NIH-funded non-human primate studies of *ImPACT* for HIV conducted by the inventor of our technology, which we believe are encouraging, have been completed.

### **Recent Developments**

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 convert into 828,889 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 will be issued an aggregate of 32,879 shares of common stock (assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus), 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.

### **Strengths and Competitive Advantages**

We believe that the following are key investment attributes of our company:

- We believe our *ImPACT* technology combines broad antigen targeting of known and unknown tumor associated antigens complexed with a potent immune adjuvant. We believe *ImPACT* has been shown to activate the immune system against a wide variety of antigens by eliciting a significant cytotoxic T cell immune response as measured by extensive pre-clinical and initial clinical immunological testing. The activated immune response generated by our *ImPACT* Therapy may be useful in treating a wide range of cancers and infectious diseases.
- We have submitted an IND and intend to initiate a Phase 2 clinical trial in NSCLC patients with our therapeutic vaccine candidate HS-110, which is derived from a genetically-modified human lung cancer cell line. We expect to initiate a Phase 1/2 clinical trial for bladder cancer with our second product candidate, HS-410, in 2H-2013.
- The National Institute of Health (NIH) and other organizations have provided significant funding to the primary inventor of the technology that we license for both his pre-clinical and clinical studies.
- Our proprietary *ImPACT* technology platform is being applied to develop multiple therapeutic vaccines against a wide range of cancers and infectious diseases. Generating positive results and gaining FDA approval for multiple therapies would lower our dependence on any one drug in order to generate returns.

- We believe our therapeutic vaccines *are easier and less expensive to manufacture than autologous vaccines* because our therapeutic vaccines do not require the harvesting of blood and/or tumor tissue from each patient in order to manufacture a course of treatment. We believe this is highly advantageous because it can bring the logistics, manufacturing, cost and distribution of our therapeutic vaccines within the purview of traditional biopharmaceutical product channels and dramatically expand our pool of corporate partners.
- We believe that we may be able to *rapidly develop new allogeneic vaccines for different types of cancers* and other diseases as our technology has the potential to be applied to many different forms of cancer.
- *Our therapies do not require an additional adjuvant*. Some vaccines require the addition of another drug, called an adjuvant, to enhance their effectiveness. Adjuvants typically cause irritation at the injection site. HS-110, one of our product candidates, is itself an adjuvant, so we do not have to use additional adjuvants to generate and maintain an activated immune response, thereby limiting any injection site reaction to that caused by our own therapies.
- *We believe our business model is capital efficient* as we continue to leverage academic and institutional resources in order to develop new products and to begin to move these products into and through clinical trials.

#### **Our Strategy**

Our strategy is to utilize our novel *ImPACT* technology platform to produce a pipeline of novel immunotherapies for the treatment of various cancers and infectious diseases and rapidly and efficiently progress these products through clinical trials towards regulatory approval. Our near term strategy includes attempting to achieve the following:

- *Develop and obtain regulatory approval for our ImPACT-based products;*
- *Maximize commercial opportunity for our ImPACT technology;*
- *Further expand our broad patent portfolio;*
- *Manage our business with efficiency and discipline;*
- *Obtain additional grant funding to more fully develop our ImPACT technology platform and its application to a variety of human diseases; and*
- *Continue to leverage and fortify our intellectual property portfolio in the US and worldwide.*

#### **Corporate Information**

We were incorporated on June 10, 2008 under the laws of the State of Delaware under the name Heat Biologics, Inc. Our executive offices are located at 100 Europa Drive, Chapel Hill, North Carolina 27517 and our telephone number is (919) 240-7133. Our website address is [www.heatbio.com](http://www.heatbio.com). The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

References to Heat Biologics also include references to our subsidiaries Heat Biologics I, Inc. (of which we own a 92.5% interest), Heat Biologics III, Inc., Heat Biologics IV, Inc. and Heat Biologics GmbH unless otherwise indicated. In June 2012, we divested our 92.5% interest in Heat Biologics II, Inc., which resulted in Heat Biologics II, Inc. being classified as discontinued operations in our consolidated financial statements for the years ended December 31, 2012 and 2011. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. We assigned our proprietary rights related to the development and application of our *ImPACT* Therapy for the treatment of non-small lung cancer to Heat Biologics III, Inc. and our proprietary rights related to the development and application of our *ImPACT* Therapy to the treatment of bladder cancer to Heat Biologics IV, Inc.

**The Offering**

Common stock offered by us(1)	2,272,727 shares
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 340,909 additional shares of our common stock from us at the initial public offering price less underwriting discounts and commissions. The option may be exercised only to cover any over-allotments
Common stock outstanding after the offering	5,856,381 shares (or 6,197,290 shares if the underwriters exercise their over-allotment option in full)
Use of Proceeds	<p>We estimate that the net proceeds from our sale of shares of our common stock in this offering will be approximately \$22.5 million, or approximately \$26.0 million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of \$11.00 per share, which is the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none"><li>· approximately \$8,350,000 to complete our Phase 2 clinical trials for HS-110 against non-small lung cancer and the submission of related materials to the FDA or an equivalent amount as grant matching funds to fund an expanded clinical trial;</li><li>· approximately \$1,000,000 for initiation and completion of Phase 1 clinical trials of HS-410 against bladder cancer;</li><li>· approximately \$100,000 to enhance the scope of and pay regulatory fees for our HS-110 lung cancer investigator-sponsored trial to test the use of HS-110 as a combination therapy against lung cancer;</li><li>· approximately \$1,500,000 to fund one to two additional Phase 1 clinical trials on additional cancer indications;</li><li>· \$300,000 to repay the portion of the loan from Square 1 Bank that is due and payable in the next eighteen months which is estimated to be \$300,000; and</li><li>· the remaining net proceeds will be used for general corporate purposes, including ongoing operations and expansion of the business, further research and development, vendor payables, potential regulatory submissions and hiring additional sales and marketing personnel to support increased sales and marketing activities.” See “Use of Proceeds.”</li></ul>
Risk Factors	See the section entitled “Risk Factors” beginning on page 9 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
NASDAQ Capital Market symbol	HTBX

The number of shares of our common stock that will be outstanding immediately after this offering is based on 3,583,654 shares of common stock outstanding as of May 21, 2013, and assumes that all outstanding shares of our convertible Preferred Stock convert into shares of our common stock upon the closing of this initial public offering and excludes:

- 662,543 shares of our common stock issuable upon the exercise of stock options as of May 21, 2013, with a weighted average exercise price of \$1.60 per share;
- 53,159 additional shares of our common stock issuable upon the exercise of outstanding warrants as of May 21, 2013, at a weighted average exercise price of \$2.16 per share; and
- 84,314 additional shares of our common stock reserved for future issuance under our equity incentive plans as of May 21, 2013.

Except for historical financial information or as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes or gives effect to:

- the conversion of all outstanding shares of our convertible Preferred Stock and the accrued dividends thereof into an aggregate of 1,688,906 shares of our common stock which will occur automatically upon the closing of this offering;
- the issuance of an aggregate of 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, (having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus), and which will occur automatically upon the closing of this offering;
- no exercise by the underwriters of their option to purchase up to 340,909 additional shares of our common stock from us in this offering; and
- no exercise of the warrants granted to Aegis Capital Corp upon completion of this offering.

We effected a 1-for-2.3 reverse stock split on May 29, 2013. Unless we indicate otherwise, all references to numbers of shares of our common stock in this prospectus reflect the effects of this reverse stock split.

#### SUMMARY CONSOLIDATED FINANCIAL DATA

The following table sets forth our summary statement of operations data for the years ended December 31, 2012 and 2011, and inception through December 31, 2012, derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus and our summary statement of operations data for the three months ended March 31, 2012 and 2013, and the balance sheet data as of March 31, 2013 from our unaudited consolidated financial statements and related notes included elsewhere in this prospectus. In our opinion, such unaudited consolidated financial statements include all adjustments consisting of only normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our consolidated financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. Our historical results are not necessarily indicative of the results to be expected for any future periods and our interim results are not necessarily indicative of the results to be expected for the full fiscal year. Pro forma net loss per common share and the pro forma balance sheet data have been calculated assuming the conversion of all outstanding shares of our Preferred Stock into 1,688,906 shares of common stock upon completion of this offering and the issuance of an additional 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this Prospectus, and which will occur automatically upon completion of this offering. The pro forma as adjusted balance sheet data reflects the balance sheet data at March 31, 2013 as adjusted to reflect our receipt of the net proceeds from the sale by us in this offering of 2,272,727 shares of common stock at an assumed initial public offering price of \$11.00 per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and conversion of all of our outstanding shares of Preferred Stock into 1,688,906 shares of common stock upon completion of this offering, the issuance of an additional 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus, and which will occur automatically upon completion this offering and the repayment of certain indebtedness. You should read this information together with the sections entitled "Capitalization," "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition & Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

**Statement of Operations Data:**

	For the Year Ended December 31,		For the Three Months Ended March 31,		Since Inception Through March 31,
	2012	2011	2013	2012	2013
			(Unaudited)		(Unaudited)
Revenues	\$ 3,110	\$ 187,787	\$ —	\$ —	\$ 585,589
Total Operating Expenses	2,345,787	2,222,587	770,482	443,629	6,851,333
Loss from Operations Before Non-Operating Expenses	(2,342,677)	(2,034,800)	(770,482)	(443,629)	(6,265,744)
Non-Operating Expenses	(108,341)	(64,182)	(17,979)	(3,419)	(245,536)
Loss from Discontinued Operations	(20,129)	(14,160)	—	(1,100)	(288,724)
Net loss	\$ (2,471,147)	\$ (2,113,142)	\$ (788,461)	\$ (448,148)	\$ (6,800,004)
Less: Net loss non-controlling interest	(50,947)	(8,258)	(24,605)	(6,464)	(100,866)
Net loss attributable to Heat Biologics, Inc. and subsidiaries	\$ (2,420,200)	\$ (2,104,884)	\$ (763,856)	\$ (441,684)	\$ (6,699,138)
Less: beneficial conversion charge	—	—	(2,300,000)	—	(2,300,000)
Net loss attributable to common stockholders	\$ (2,420,200)	\$ (2,104,884)	\$ (3,063,856)	\$ (441,684)	\$ (8,999,138)
Net (loss) per share:					
Basic	\$ (1.32)	\$ (1.15)	\$ (1.66)	\$ (0.24)	
Diluted	\$ (1.32)	\$ (1.15)	\$ (1.66)	\$ (0.24)	
Weighted average shares of common stock outstanding used in computing net (loss) per share:					
Basic	1,831,769	1,824,927	1,859,929	1,830,597	
Diluted	1,831,769	1,824,927	1,859,929	1,830,597	
Pro forma net (loss) per share of common stock:					
Basic	\$ (0.42)	\$ (0.36)	\$ (0.52)	\$ (0.08)	
Diluted	\$ (0.42)	\$ (0.36)	\$ (0.52)	\$ (0.08)	
Weighted average shares of common stock outstanding used in computing pro forma net (loss) per share:					
Basic	5,826,281	5,819,439	5,854,441	5,825,109	
Diluted	5,826,281	5,819,439	5,854,441	5,825,109	

**Balance Sheet Data:**

	As of March 31, 2013	
	Actual	Pro Forma As Adjusted(1)
	(Unaudited)	
Cash and Cash Equivalents	\$ 4,889,723	\$ 27,089,720
Total Current Assets	5,102,966	27,302,963
Total Assets	5,175,969	27,375,966
Total Current Liabilities	1,373,043	1,073,043
Long Term Liabilities	1,158,934	1,158,934
Total Stockholders' Equity	\$ 2,643,992	\$ 25,143,989

- (1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share of our common stock, the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) each of cash, total assets, and total stockholders' equity (deficit) by \$2,090,909 assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

## 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 occurs, 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 prospectus 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, as described herein, 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 or even to make quarter to quarter comparisons of our operating results. You 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:

- continuing to undertake pre-clinical development and initiate clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- 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. At the conclusion of this offering, we believe we will have 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 three months ended March 31, 2013 and March 31, 2012, we incurred a net loss attributable to Heat Biologics, Inc. and Subsidiaries of (\$763,856) and (\$441,684), 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 an accumulated deficit since inception of (\$6,699,138). 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:

- continue to undertake pre-clinical development and initiate clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- 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.

***If we default on our secured loans with Square 1 Bank, we would be forced to suspend all operations.***

We have entered into loans with Square 1 Bank that are secured by substantially all of our assets, excluding our intellectual property. Our loan agreement with Square 1 Bank sets forth various affirmative and negative covenants that we must comply with, including covenants regarding financial reporting, limits on our cash burn, incurrence of indebtedness and liens and merger and acquisitions. If we fail to comply with these covenants or if we fail to make timely monthly payments under the secured loans when due, Square 1 Bank could declare our loans in default. Additionally, if we do not commercialize a product by the maturity date of the loan, we may be unable to repay the loans to Square 1 Bank. If we default on the loans, Square 1 Bank has the right to seize the collateral secured by the loans, which would result in our licenses reverting back to our licensor and would force us to suspend all operations. In order to comply with the covenants of the loans and to make timely payments to Square 1 Bank under the loans, we may need to raise additional capital, which might not be available to us on favorable terms or at all.



## **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 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:

- prevent or delay commercialization of, and our ability to derive product revenues from, our product candidates; and
- 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. We cannot assure you 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 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:

- unforeseen safety issues;
- failure to determine appropriate dosing;
- greater than anticipated cost of our clinical trials;
- failure to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment or difficulty obtaining investigators;
- patient drop-out or discontinuation;
- inability to monitor patients adequately during or after treatment;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;
- 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;
- problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;
- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and
- 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 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:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- limitation on use or warnings required by FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- 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:

- the development of certain of our current or future product candidates may be terminated or delayed;
- 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;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates;
- 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:

- developing drugs, biologics and other therapies;
- undertaking pre-clinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs, biologics and other therapies;
- formulating and manufacturing drugs, biologics and other therapies; and
- 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:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug or therapy candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- 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:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- 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, uncertainty 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 at the completion of this offering, 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:

- decreased demand for any approved product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- 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:

- 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;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our product candidates in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- limits on our ability to penetrate international markets if our product candidates cannot be processed by a manufacturer appropriately qualified in such markets;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- 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 this Offering

### *Upon the sale of the shares offered in this prospectus, our Preferred Stock will convert into shares of common stock*

Holders of our Preferred Stock have several rights that our common shareholders do not have such as preference on payment of dividends and liquidation distributions, the right to elect a certain number of directors, the right to adjustment in the event that securities are issued at a price per share less than that paid by the holders of the Preferred Stock. Our Third Amended and Restated Certificate of Incorporation provides that our Preferred Stock automatically converts to common stock upon the earlier of: (i) a closing of a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$15,000,000 of net proceeds to us; (ii) with respect to the Series 1 Preferred Stock, written consent or agreement of at least two-thirds of the then outstanding shares of Series 1 Preferred Stock; (iii) with respect to the Series A Preferred Stock, written consent or agreement of at least two-thirds of the then outstanding shares of Series A Preferred Stock (which must include the lead investor if it meets certain criteria); (iv) with respect to the Series B-1 Preferred Stock, written consent or agreement of at least two-thirds of the then outstanding shares of Series B-1 Preferred Stock; and (v) with respect to the Series B-2 Preferred Stock, written consent or agreement of at least two-thirds of the then outstanding shares of Series B-2 Preferred Stock. Upon the conversion of the Preferred Stock the holders of common stock will experience additional dilution.

### *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.*

Our officers and directors together will control approximately 37.0% of our outstanding common stock on a fully diluted basis after consummation of this offering assuming the issuance of all 2,272,727 shares of common stock offered in this offering. Mr. Wolf alone through his direct and indirect holdings will control approximately 22.6% of our outstanding common stock on a fully diluted basis after consummation of this offering assuming the issuance of all 2,272,727 shares of common stock offered in this offering. 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, 662,543 options were outstanding as of May 21, 2013. In addition, as of May 21, 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. 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. The classes of Preferred Stock that are currently outstanding, which will convert to common stock upon consummation of this offering, rank ahead of our common stock in terms of dividends, liquidation rights and voting rights and could adversely affect the voting power and the rights of our holders of 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. See “Dividend Policy.”

***Shareholders purchasing shares in this offering will experience immediate and substantial dilution, causing their investment to immediately be worth less than their purchase price.***

If you purchase common stock in this offering, you will experience an immediate and substantial dilution in the projected book value of the common stock from the price you pay in this offering.

After consummation of this offering and assuming the consummation of this offering and conversion of all of the outstanding Preferred Stock exclusive of the over-allotment option, you will have an immediate dilution of \$6.71 per common share and an immediate increase in net tangible book value to our present shareholders from \$0.74 to \$4.29 per share will occur.

***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 our becoming a public company, we will become subject to additional reporting and corporate governance requirements that will require additional management time, resources and expense.***

In connection with this filing, we will become 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 will also become 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 will 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. We have historically 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 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. Regardless, following the completion of this offering 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.***

The Company will have a significant number of restricted shares that will become eligible for sale shortly after this registration statement is declared effective. We currently have 1,861,869 shares of our common stock outstanding, 1,975,628 shares of Series A and Series 1 Preferred Stock outstanding that converts to 860,017 shares of common stock, 1,891,419 shares of Series B-1 Preferred Stock outstanding that together with accrued dividends converts to 828,889 shares of common stock and an additional 32,879 shares of common stock that will be issued to investors of our Series B-1 Preferred Stock upon consummation of this offering (assuming an initial public offering of \$11.00 per share, which is the midpoint of the range set forth on the cover page of this prospectus), all of which will be restricted securities. All of the 2,272,727 shares sold in this offering will be eligible for sale immediately upon effectiveness of this registration statement. All of the remaining shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date, of this prospectus, 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 you to lose part or all of your investment in our shares of common stock.

***Our common stock may be thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.***

Prior to this offering, you could not buy or sell our common stock publicly. We cannot predict the extent to which investors' interests will lead to an active trading market for our common stock or whether the market price of our common stock will be volatile following this offering. If an active trading market does not develop, investors may have difficulty selling any of our common stock that they buy. There may be limited market activity in our stock and we are likely to be too small to attract the interest of many brokerage firms and analysts. We cannot give you any assurance that a public trading market for our common stock will develop or be sustained. The market price of our common stock could be subject to wide fluctuations in response to quarterly variations in our revenues and operating expenses, announcements of new products or services by us, significant sales of our common stock, including "short" sales, the operating and stock price performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets or general economic conditions.

***The offering price of the shares may not be indicative of the value of our assets or the price at which shares can be resold.***

The offering price of the common stock may not be an indication of our actual value. Prior to this offering, there has been no public market for our securities. The offering price of \$11.00 per share was determined based upon negotiations between the underwriters and us. Factors considered in determining such price in addition to prevailing market conditions include an assessment of our future prospects, an increase in value of our stock due to becoming a public company and prior valuations of certain minority interests prepared for us. Such price does not have any relationship to any established criteria of value, such as book value or earnings per share. Such price is not indicative of the current market value of our assets. No assurance can be given that the shares can be resold at the public offering price.

***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 derived from the sale of the shares in this 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 clinical trial for bladder cancer. Thereafter, we expect to require additional funds in the future to conduct additional clinical trials even if the maximum amount is raised in this offering. There are no other commitments by any person for future financing other than a loan from Square 1 Bank for an amount up to \$3,000,000; however in order to continue to borrow under the loan there are several conditions which must be met and there can be no assurance that we will meet such conditions or be able to borrow the entire \$3,000,000. There can be no assurance given that we will meet these closing conditions. Through May 21, 2013, we have outstanding \$725,000 under our loan from Square 1 Bank. Our securities may be offered to other investors at a price lower than the price per share offered to the investors in the offering, or upon terms which may be deemed more favorable than offered hereunder. In addition, the issuance of securities in this offering as well as any future financing using our securities 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, including the investors in this offering. 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.

***We have adopted certain measures that may have anti-takeover effects which may make an acquisition of our Company by another company more difficult.***

We have adopted, and may in the future adopt, certain measures that may have the effect of delaying, deferring or preventing a takeover or other change in control of our Company that a holder of our common stock might not consider in its best interest. Our certificate of incorporation and bylaws contain provisions which may have anti-takeover effects. These include: (a) requiring that certain shareholder groups elect a certain number of directors for so long as certain shares of preferred stock remain outstanding; (b) requiring that for so long as any shares of Preferred Stock remain outstanding a majority of each of the Series B Preferred shareholders, Series A Preferred shareholders, the Series 1 Preferred shareholders and the common shareholders approve certain actions including: (i) amendments to our bylaws or certificate of incorporation, unless in connection with a Qualified Public Offering; (ii) creation of additional classes of stock or increases in the authorized shares of an existing class of stock unless they rank junior to the Series A Preferred Stock with respect to the distribution of assets on liquidation and the

payment of dividends, reclassification stock or redemption of stock, unless in connection with a Qualified Public Offering; (iii) action to reclassify, alter or amend existing securities that are junior to or *pari passu* with the Series A Preferred if such action would render such security senior to *opari passu* with the Series A Preferred Stock in respect of the distribution of assets upon liquidation or payment of a dividend other than with respect to a firm commitment underwritten public offering with net proceeds to us of at least \$15,000,000, unless in connection with a Qualified Public Offering; (iv) purchase or redeem or otherwise declare or pay a dividend, unless in connection with a Qualified Public Offering; (v) action to liquidate or sell all or; (vi) substantially all of our assets; (c) requiring that for so long as a majority of the originally issued shares of Series B Preferred Stock remain outstanding and until we receive \$20,000,000 through financing, grant or a licensing or joint venture agreement a majority of Series B Preferred shareholders must give prior approval of certain actions including: (i) operation of any business other than our business as carried out on the date the Series B-1 Preferred Stock was originally issued; (ii) making of a loan to any entity or subsidiary other than an 80% owned subsidiary, (iii) disposition or acquisition of an interest in a business (except to the extent that prior approval of the board of directors is received including the director nominated by the Series B Preferred Stockholders); (iv) entering into a joint venture or making an investment in excess of \$5,000,000 (except to the extent that prior approval of the board of directors is received including the director nominated by the Series B Preferred Stockholders); (v) making or committing to make an expenditure of \$5,000,000 or more (except to the extent that prior approval of the board of directors is received including the director nominated by the Series B Preferred Stockholders); (vi) making a loan of in excess of \$5,000 (except to the extent that prior approval of the board of directors is received including the director nominated by the Series B Preferred Stockholders); (vii) issuing debt in excess of \$5,000,000 other than under existing agreements (except to the extent that prior approval of the board of directors is received including the director nominated by the Series B Preferred Stockholders); and (viii) an annual budget. These measures and those described above may have the effect of delaying, deferring or preventing a takeover or other change in control of the Company that a holder of our common stock might consider in its best interest.

In addition, 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.

***Our management will have broad discretion over the use of the proceeds we receive in this offering, and may not apply the proceeds in ways that increase the value of your investment.***

If the underwriters exercise their option to purchase additional shares in this offering in full, we estimate that net proceeds of the sale of the common stock that we are offering will be approximately \$26.0 million. Our management will have broad discretion to use the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Although we intend to use a portion of the net proceeds from this offering for research, development and commercialization of our products and payment of outstanding indebtedness, because of the number and variability of factors that will determine our use of the net proceeds from this offering, we cannot specify with certainty the particular use of the net proceeds that we will receive from this offering, and we cannot assure you that we will use the proceeds in a manner that will increase the value of your investment or of which you would approve. Moreover, you will not have the opportunity to influence our decision on how to use the proceeds from this offering. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. See the Section entitled "Use of Proceeds."



## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, including statements regarding the progress and timing of our product development, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, our expected future revenues, operations and expenditures and projected cash needs. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements relate to future events of our financial performance and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. Those risks and uncertainties include, among others:

- our ability to implement our business plan;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to generate product revenues;
- our ability to achieve profitability;
- our ability to comply with our loan covenants;
- our ability to satisfy U.S. (including FDA) and international regulatory requirements;
- our ability to obtain market acceptance of our technology and products;
- our ability to compete in the market;
- our ability to advance our clinical trials;
- our ability to fund, design and implement clinical trials;
- our ability to maintain our present customer base and retain new customers;
- our ability to demonstrate that our product candidates are safe for human use and effective for indicated uses;
- our ability to gain acceptance of physicians and patients for use of our products;
- our dependency on third-party researchers and manufacturers and licensors;
- our ability to establish and maintain strategic partnerships, including for the distribution of products;
- our ability to attract and retain a sufficient qualified personnel;
- our ability our ability to obtain or maintain patents or other appropriate protection for the intellectual property;
- our dependency on the intellectual property licensed to us or possessed by third parties;
- our ability to adequately support future growth; and
- potential product liability or intellectual property infringement claims.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential,” or the negative of those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. You should read this prospectus and the documents referenced in this prospectus and filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

## USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$22.5 million from the sale of shares of common stock offered in this offering, or approximately \$26.0 million if the underwriters exercise their over-allotment option in full, based on an assumed initial public offering price of \$11.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$2,090,909 assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. An increase (decrease) of 454,545 in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$4.6 million, assuming the initial public offering price per share stays the same. An increase of 454,545 in the number of shares we are offering, together with a \$1.00 increase in the assumed initial public offering price per share, would increase the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$7.1 million. A decrease of 454,545 in the number of shares we are offering, together with a \$1.00 decrease in the assumed initial public offering price per share, would decrease the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$6.3 million. The foregoing assumes no exercise of the underwriters' over-allotment option. We do not expect that a change in the offering price per share or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

We intend to use the net proceeds from this offering as follows:

- approximately \$8,350,000 to complete our Phase 2 clinical trials for HS-110 against non-small lung cancer and the submission of related materials to the FDA or an equivalent amount as grant matching funds to fund an expanded clinical trial. We plan to initiate a 125 patient Phase 2 trial on patients with advanced non-small cell lung cancer. Our Phase 2 study has been designed as a maintenance therapy study in patients with Stage III/IV NSCLC who have completed a 1<sup>st</sup> line regimen consisting of a platinum doublet, crizotinib or erlotinib and achieved at least stable disease. We plan to use up to approximately \$8.35 million from the net proceeds of this offering to finance this trial. We have applied for grant funding to enable us to expand the size and scope of this clinical trial and if the grant funding is received, will use up the \$8.35 million of the net proceeds from this offering as "matching funds" as required by the granting organization to expand the size and scope of our trial. There can be no assurance that the grant funding will be received. If sufficient grant funding is not received by the commencement of the trial to fund the trial, we will use the net proceeds of this offering to provide the needed funding for a 125 patient Phase 2 trial;
- approximately \$1,000,000 for initiation and completion of Phase 1/2 clinical trials of HS-410 against bladder cancer. We plan to file an IND for use of HS-410 to prevent the recurrence of bladder cancer. This initial IND will include a 93 patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 6 weekly intravesical bacillus Calmet-Guerin (BCG) immunotherapy installations. We plan to use approximately \$1 million from the net proceeds of this offering to enhance the scope of this trial as currently designed and funded;
- approximately \$100,000 to enhance the scope of and pay regulatory fees for our HS-110 lung cancer investigator-sponsored trial to test the use of HS-110 as a combination therapy against lung cancer. Our HS-110 lung cancer trial is an investigator-sponsored trial to test the use of HS-110 as a combination therapy against lung cancer. While the trial is fully-funded by the Marcus Foundation, we plan to use approximately \$100,000 to enhance the scope of this trial and prepare appropriate regulatory filings;

- approximately \$1,500,000 to fund one to two additional Phase 1 clinical trials on additional cancer indications. We are creating and have created *ImPACT*-based drugs against additional cancers and plan to use approximately \$1.5 million from the net proceeds of this offering to fund one to two additional Phase 1 clinical trials on additional cancer indications;
- \$300,000 to repay the portion of the loan from Square 1 Bank that is due and payable in the next eighteen months. We plan to use approximately \$300,000 of the net proceeds of this offering to repay the portion of the loans from Square 1 Bank that is due and payable in the next eighteen months. One loan from Square 1 Bank is payable on September 7, 2013 in 36 monthly installments of principal and interest and accrues interest monthly at an interest rate of 3% plus prime or 6% per annum whichever is greater. The other loan is payable on August 7, 2013 and August 7, 2014 for 5% of the outstanding principal and accrued interest each and then the remaining principal and accrued interest is due December 14, 2014 and accrues interest at 4.25%. Finally, the last loan is payable as interest only until January 9, 2014 when the entire principal balance is due and it accrues interest monthly at an annual rate of 0.75% plus prime or 4% per annum, whichever is greater. As of May 21, 2013, we had outstanding \$725,000 under the Square 1 Bank loans; and
- the remaining net proceeds will be used for general corporate purposes, including ongoing operations, vendor payables and expansion of the business, further research and development, potential regulatory submissions and hiring additional sales and marketing personnel to support increased sales and marketing activities.

The expected use of the net proceeds from this offering represents our current intentions based on our present plans and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received from this offering. The amounts and timing of our actual expenditures will depend on numerous factors including the progress in, and costs of, our clinical trials and other preclinical development programs and the amount of funding, if any, received from grants. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of management regarding the application of the net proceeds from the offering. We may find it necessary or advisable to reallocate the net proceeds of this offering; however any such reallocation would be substantially limited to the categories set forth above as we do not intend to use the net proceeds for other purposes. Pending such uses set forth above, we plan to invest the net proceeds in government securities and other short-term investment grade, marketable securities.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends, if any, on our common stock will be at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents as well as capitalization as of March 31, 2013:

- on an actual basis;
- on a pro forma basis as of March 31, 2013, to reflect the automatic conversion upon the closing of this offering of all outstanding shares of Preferred Stock including accrued dividends into 1,688,906 shares of common stock and to reflect the issuance of an additional 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus, and which will occur automatically upon completion of this offering;
- on a pro forma as-adjusted basis to (i) give effect to the sale of 2,272,727 shares of the common stock we are offering at an assumed initial public offering price of \$11.00 per share, which is the midpoint of the estimated price range shown on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us and (ii) the use of \$300,000 in proceeds to repay the portion of the loan from Square 1 Bank that is due and payable within the next 18 months. The pro forma as-adjusted column assumes no exercise by the underwriters of their over-allotment option.

The information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public price. You should read this table together with the sections entitled "Use of Proceeds" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as our financial statements and the related notes, which appear elsewhere in this prospectus.

	As of March 31, 2013		
	(unaudited)		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
<i>(\$ in thousands)</i>			
Cash and cash equivalents	<u>\$ 4,889,723</u>	<u>\$ 4,889,723</u>	<u>\$ 27,089,720</u>
Long term debt, including current portion	1,390,106	1,390,106	1,090,106
Convertible Preferred Stock, Series A 2,000,000 shares authorized, 1,863,128 shares issued and outstanding, actual; 2,000,000 shares authorized, no shares issued and outstanding, pro forma; 2,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	186	—	—
Convertible Preferred Stock, Series 1 112,500 shares authorized, 112,500 shares issued and outstanding, actual; 112,500 shares authorized, no shares issued and outstanding, pro forma; 112,500 shares authorized, no shares issued and outstanding, pro forma as adjusted	11	—	—
Convertible Preferred Stock, Series B 4,100,000 shares authorized, 1,891,419 shares issued and outstanding, actual; 4,100,000 shares authorized, no shares issued and outstanding, pro forma; 4,100,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	189	—	—

	As of March 31, 2013		
	(unaudited)		
	Actual	Pro Forma	Pro Forma As Adjusted(1)
<i>(\$ in thousands)</i>			
Common stock, 50,000,000 shares authorized, 2,144,533 and 1,861,137 shares issued and outstanding, respectively, actual; 50,000,000 shares authorized, 1,861,869 shares issued and outstanding, pro forma; 50,000,000 shares authorized, 5,856,381 shares issued and outstanding, pro forma as adjusted	405	799	1,254
Additional paid in capital	9,443,205	9,443,197	31,942,739
Accumulated deficit	(6,699,138)	(6,699,138)	(6,699,138)
Non-Controlling Interest	(100,866)	(100,866)	(100,866)
Total stockholders' equity	<u>2,643,992</u>	<u>2,643,992</u>	<u>25,143,989</u>
Total capitalization	<u>\$ 4,034,098</u>	<u>\$ 4,034,098</u>	<u>\$ 26,234,095</u>

- (1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share of our common stock, the midpoint of the estimated price range set forth on the cover page of this prospectus, in this offering would increase (decrease) each of cash, total stockholders' deficit and total capitalization by \$2,090,909 assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of common stock to be outstanding after the offering is based on the number of shares outstanding as of March 31, 2013, and excludes:

- 662,543 shares of our common stock issuable upon the exercise of stock options as of May 21, 2013, with a weighted average exercise price of \$1.60 per share;
- 53,159 additional shares of our common stock issuable upon the exercise of outstanding warrants as of May 21, 2013, at a weighted average exercise price of \$2.16 per share;
- 84,314 additional shares of our common stock reserved for future issuance under our equity incentive plans as of May 21, 2013;
- up to 340,909 additional shares of common stock issuable upon exercise of the underwriters' over-allotment option; and
- 113,636 shares of our common stock issuable upon exercise of the warrants granted to Aegis Capital Corp. upon completion of this offering.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and our pro forma as adjusted net tangible book value per share immediately after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities less debt discounts related to debt to be paid or converted as a result of this offering, by the number of outstanding shares of our common stock. Prior to considering the effects of the proceeds of this offering, but giving effect to the automatic conversion of our outstanding shares of Series A, Series I and Series B Preferred Stock into 1,688,906 shares of our common stock upon completion of this offering and the issuance of an additional 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus, and which will occur automatically upon completion of this offering, our pro forma net tangible book value (deficit) as of March 31, 2013 was approximately \$2,643,992, or approximately \$0.74 per share. Upon completion of this offering, our pro forma as adjusted net tangible book value as of March 31, 2013 will be approximately \$25,143,989 or approximately \$4.29 per share. This represents an immediate increase in pro forma net tangible book value of \$3.55 per share to our existing stockholders and an immediate dilution of \$6.71 per share to new investors purchasing our common stock in this offering. The following table illustrates the per share dilution:

Assumed initial public offering price per share	\$ 11.00
Pro forma net tangible book value per share as of March 31, 2013	\$ 0.74
Increase in pro forma net tangible book value per share after this offering	\$ 3.55
Pro forma as adjusted net tangible book value per share after this offering	<u>4.29</u>
Dilution in pro forma net tangible book value per share to new investors	<u>\$ 6.71</u>

Each \$1.00 increase in the assumed initial public offering price of \$11.00 per share, the midpoint of the range set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value by approximately \$2.091 million, the pro forma as adjusted net tangible book value per share by approximately \$0.36 per share and the dilution to investors purchasing shares of our common stock in this offering by approximately \$0.64 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 decrease in the assumed initial public offering price of \$11.00 per share, the midpoint of the range set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value by approximately \$2.091 million, the pro forma as adjusted net tangible book value per share by approximately \$0.36 per share and the dilution to investors purchasing shares of our common stock in this offering by approximately \$0.64 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$4.61 per share, representing an immediate increase in pro forma as adjusted net tangible book value to existing stockholders of \$3.87 per share and an immediate dilution of \$6.39 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

The following table summarizes, on a pro forma as adjusted basis as of March 31, 2013, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed initial public offering price of \$11.00 per share, the midpoint of the estimated price range shown on the cover page of this prospectus.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	%	Amount	%	
Existing stockholders	3,583,654	61	\$ 9,224,449	29	\$ 2.57
New investors	2,272,727	39	22,499,997	71	9.90
Total	<u>5,856,381</u>	<u>100.0</u>	<u>\$ 31,724,446</u>	<u>100.0</u>	\$ 5.42

The number of shares purchased from us by existing stockholders is based on 3,583,654 shares of our common stock outstanding as of March 31, 2013 after giving effect to the automatic conversion of all of our outstanding shares of Series A Preferred Stock, Series 1 Preferred Stock and Series B Preferred Stock into common stock upon the completion of this offering and the issuance of an additional 32,879 shares of common stock to the investors of our Series B-1 Preferred Stock, having a value of \$361,668 assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus, and which will occur automatically upon completion. This number excludes:

- 662,543 shares of our common stock issuable upon the exercise of stock options as of May 21, 2013, with a weighted average exercise price of \$1.60 per share
- 53,159 additional shares of our common stock issuable upon the exercise of outstanding warrants as of May 21, 2013, at a weighted average exercise price of \$2.16 per share;
- 84,314 additional shares of our common stock reserved for future issuance under our equity incentive plans as of May 21, 2013; and
- 113,636 shares of our common stock issuable upon exercise of the warrants granted to Aegis Capital Corp. upon completion of this offering.

If the underwriters exercise their option to purchase additional shares from us in full, the number of shares held by new investors will increase to 2,613,636, or 42% of the total number of shares of common stock outstanding after this offering and the shares held by existing stockholders will be 3,583,654 but the percentage of shares held by existing stockholders will decrease to 58% of the total shares outstanding.

To the extent that the underwriters' over-allotment option is exercised or any warrants or options are exercised, there will be further dilution to new investors.



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

*The following discussion and analysis should be read in conjunction with our audited annual consolidated financial statements and the related notes that appear elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled "Risk Factors", "Special Note Regarding Forward-Looking Statements" and elsewhere in this prospectus.*

### 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*<sup>™</sup> cancer 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. The secreted antigen-adjuvant complexes are designed to generate an anti-cancer immune response in patients by mobilizing and activating killer T cells that target multiple cancer antigens, thus harnessing a patient's own immune system to fight cancer. Based on results from a Phase 1 clinical trial in non-small cell lung cancer patients (NSCLC) conducted by the primary inventor of the technology that we license, in which 18 patients were vaccinated and 15 patients completed the first of three planned courses of therapy and were evaluated, we believe there is clinical evidence that the "off-the-shelf" therapeutic vaccine candidate HS-110 is capable of generating anti-cancer immune responses. Specifically, the trial observed a response in 11 of 15 patients. These findings were consistent with those of multiple pre-clinical published studies. HS-110 showed no overt toxicity.

As an "off-the-shelf" therapeutic vaccine, *ImPACT* uses a common master cell line to mass-produce a single vaccine product applicable to all patients for each particular cancer type, and thus, we believe, providing a traditional biopharmaceutical approach to deliver pan-antigen immunotherapy with logistical, manufacturing and cost of goods benefits compared to autologous patient-specific approaches.

We have submitted an IND to initiate a Phase 2 clinical trial in non-small cell lung cancer (NSCLC) with our therapeutic vaccine candidate HS-110, which is derived from a genetically-modified human lung cancer cell line.

We are also developing *ImPACT* therapeutic vaccines for bladder cancer, breast cancer and ovarian cancer. We plan to initiate a Phase 1/2 clinical trial for bladder cancer in Q3-2013 with HS-410, a genetically-modified bladder cancer cell line. To date, in excess of \$14,000,000 of funding has been awarded to the primary inventor of the technology that we license by the National Institutes of Health (NIH) and through other research and clinical grant in order to fund development of the technology that 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. Our strategy is to continue to apply for grants that will enable us to leverage our core technology platform. Our primary inventor also applies for academic grants to enhance the core technology platform. Grant funds received by our primary inventor are not utilized by us. Rather, these funds support our primary inventor's academic interests and may benefit us to the extent that these grants enable him to enhance the technology platform or generate additional data to support our programs. Currently, our primary inventor's academic grants are supporting the HS-110 NSCLC combination study as well as the HIV study. Our Phase 2 NSCLC study and our Phase 1/2 bladder cancer study are supported by us.

The actual amount of funds we will need to complete our 93-patient, Phase 1/2 trial of HS-410 is estimated to be \$3.5 million of which \$1,000,000 will be derived from the net proceeds of this offering and is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the progress and cost of our research and development activities;
- the number and scope of our research and development programs;

- the progress and cost of our preclinical and clinical development activities;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

#### **Recent Developments**

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 offering. All shares of Series B Preferred Stock automatically convert into shares of our common stock upon the consummation of a Qualified Public Offering. In addition, upon consummation of a Qualified Public Offering, the investors will be issued an aggregate of 32,879 shares of common stock (assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth on the cover page of this prospectus), and our obligation to issue, and the investors' obligation to purchase, Series B-2 Preferred Stock and warrants upon fulfillment of the conditions specified in our Stock Purchase Agreement with the investors will be terminated.

#### **Critical Accounting Policies**

##### *Revenue Recognition*

We recognize government grants when there is reasonable assurance that they will comply with the conditions attached to the grants and that the grants will be received. The grants are recognized using an income approach and grant revenue is recognized as the related expenses are incurred.

##### *Stock Based Compensation*

We account for stock-based compensation arrangements with employees and non-employee directors using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires us to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model. Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The expected term for the years ended December 31, 2012 and 2011 represents the average time that options are expected to be outstanding based on the mid-point between the vesting date and the end of the contractual term of the award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We have not paid dividends and do not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. The measurement of nonemployee share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are received.

The fair value of the common stock underlying our stock options was determined at each grant date by our board of directors and supported by periodic independent third-party valuations. Our board of directors intended all options to be exercisable at a price per share not less than the per share fair value price of our common stock underlying those options on the date of grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. For grants of stock awards made on dates for which there was no valuation performed by a valuation specialist, our board of directors determined the fair value of our common stock on the date of grant based upon the immediately preceding valuation and other pertinent information (such as significant changes in our activities) available at the time of grant.

We have granted stock options during the period from January 1, 2011 through May 21, 2013 as summarized below:

<u>Option Grant Dates:</u>	<u>Number of Options Granted</u>	<u>Exercise Price Per Share</u>	<u>Common Stock Fair Value Per Share At Grant Date</u>	<u>Fair Value Per Option</u>
April 7, 2011	12,610	\$0.64	\$0.64	\$0.3857
April 7, 2011	108,696	\$0.71	\$0.64	\$0.3172
April 12, 2011	141,852	\$0.64	\$0.64	\$0.3926
October 25, 2011	20,871	\$0.64	\$0.64	\$0.4338
October 25, 2011	6,522	\$0.64	\$0.64	\$0.4683
October 25, 2011	21,740	\$0.64	\$0.64	\$0.3857
November 22, 2011	21,740	\$0.64	\$0.64	\$0.4071
April 25, 2012	98,087	\$0.76	\$0.76	\$0.4356
April 25, 2012	2,174	\$0.76	\$0.76	\$0.4526
May 30, 2012	1,305	\$0.76	\$0.76	\$0.4526
November 8, 2012	77,176	\$0.76	\$2.23	\$1.4009
April 29, 2013	34,132	\$8.81	\$8.81	\$6.4057
May 15, 2013	38,364	\$8.81	\$8.81	\$6.4959

Four valuations were performed by independent valuation specialists on March 31, 2011, March 31, 2012, December 31, 2012 and March 31, 2013.

To determine the fair value of the common stock, we considered three enterprise value allocation methods consistent with the American Institute of Certified Public Accountants Practice Aid, "Valuation of Privately-Held Company Equity Securities Issued as Compensation." These methods are: (i) current-value method; (ii) the option pricing method; and (iii) the probability-weighted expected return method. Under the option pricing method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preference at the time of a liquidity event. The option-pricing method uses the Black-Scholes option model to price the call options. After considering several factors and circumstances, we utilized the option pricing backsolve method. The option pricing backsolve method treats common stock and Preferred Stock as call options on the enterprise/equity value, with exercise prices based on the liquidation preference of the Preferred Stock.

In order to estimate the fair value of the equity as of March 31, 2011, we did an option pricing backsolve method based on the recently issued convertible note. In May 2010 and September 2010, we completed the issuance of convertible promissory notes with an unrelated party which was considered to be at "arms-length." We estimated the implied equity value to be approximately \$3.4 million as of March 31, 2011. After consideration of specific facts and circumstances, the board of directors and management assumed a 3.5 years to a liquidity event. The anticipated timing and probability of a liquidity event was based on then-current plans and estimates of our board of directors and management regarding a liquidity event. Furthermore, volatility was estimated based on 3.5-year historical volatility of peer companies. To derive the value of the common stock, the proceeds to the common stockholders were calculated based on the preferences and priorities of the preferred and common stock, including the participation features of certain series of the preferred shares. A discount in the amount of 40% for lack of marketability was applied to reflect the risk arising from the inability to readily sell the shares. The discount for lack of marketability was based on our size, pre-profit stage, attraction to outside investors, and expectation of liquidity. After applying the 40% discount for lack marketability, we concluded the fair value of our common stock on a minority, non-marketable basis to be \$0.64 per share.

To determine the fair value of our common stock as of March 31, 2012, we considered two scenarios based on the specific facts and our circumstances as of March 31, 2012. As of March 31, 2012, we had specific needs of cash in order to continue operations. As such, we were planning a series B round of financing. Based on the specific facts and circumstances, the first scenario assumes we will raise the Series B round of financing ("Going Concern") and the second scenario assumes the Company will liquidate in the next three months ("Liquidation Scenario").

Under the first scenario, the fair value of the common stock was determined by applying the option pricing backsolve method. A 5-year to liquidity was assumed by management and the board of directors based on the anticipated timing and probability of a liquidity event. Volatility was assumed based on historical volatility of peer companies. In order to estimate the implied equity value, we assumed terms and conditions based on the Series B round of financing. An option pricing backsolve method was applied to determine the value of the equity based on

the anticipated Series B round of financing, which was expected to occur during the latter half of 2012 with an unrelated investor. Under the second scenario, the fair value of the common stock was determined by applying the current method given the immediate liquidity event. Our management and our board of directors (the "Board") assumed that we will liquidate in the next three months. Given the facts and circumstances, we assumed that there would be no proceeds available for distribution to the common stockholders, indicating the fair value of the common stock to be zero. After considering both scenarios, a weighted average of the current value approach and the OPM was calculated to estimate the fair value of the common stock as of March 31, 2012. A discount in the amount of 40% for lack of marketability was applied to reflect the risk arising from the inability to readily sell the shares. The discount for lack of marketability was based on our size, pre-profit stage, attraction to outside investors, and expectation of liquidity. After applying the 40% discount for lack marketability present in the common stock, we concluded the fair value of our common stock on a minority, non-marketable basis to be \$0.76 per share.

To determine the fair value of the common stock as of December 31, 2012, we utilized the probability-weighted return method ("PWERM") to allocate the total equity value to the various securities, including Preferred Stock warrants. The PWERM model reflected our continued development, including the anticipation of the closing of Series B-1 convertible Preferred Stock financing. In addition, the model took into account the additional funding we received from our loan agreement that was entered into with Square 1 Bank in August 2012, the progression of our HS-110 program for non-small cell lung cancer and our HS-410 program for bladder cancer and notification that we were being considered as a candidate for potential grant funding for our non-small cell lung cancer program since the previous valuation dated March 31, 2012. The revision of our HS-110 clinical trial protocol, to remove a combination therapy from our clinical protocol, enhanced the universe of potential patients for our lung cancer drug and the potential market for the drug, resulting in a material increase in investor interest in our company. At that time, we also retained a nationally recognized bladder cancer oncologist to assist in designing our clinical trials and progressing our development plans, resulting in an enhancement of our oncology capabilities and diversification of our development activities, which also assisted our attractiveness as a financing candidate. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of four future scenarios: an immediate IPO, a delayed IPO, a sale or merger, or liquidation. The equity is allocated pro rata among the total common shares on as-converted basis. The value per share under each scenario was then probability weighted and the resulting weighted values were summed to determine the fair value per share for each class. Our calculated discounts for the lack of marketability through the use of the Black-Scholes-Option Pricing Model, and applied an implied discount for marketability of 20.5% for the immediate IPO scenario, 29% for the delayed IPO scenario, and 61.7% for the sale or merger scenario. The expected outcomes were weighted based on a probability of forty percent (40%) for the liquidation scenario, with a lower probability for an IPO scenario of twenty-five percent (25%) and a probability of thirty-five percent (35%) for the sale or merger scenario. The fair values of the equity determined using the IPO and non-IPO scenarios were weighted according to our estimate of the probability of each scenario. Based on the PWERM model, the Board of Directors determined the fair value of our common stock at December 31, 2012 to be \$2.23.

To determine the fair value of the common stock as of March 31, 2013, we utilized a combination of factors including, the probability-weighted return method ("PWERM") to allocate the total equity value to the various securities, including Preferred Stock warrants. The PWERM model reflected our continued development, including the anticipation of the closing of Series B-1 convertible Preferred Stock financing. The other significant factors were the consummation of our Series B Preferred Stock private placement and our progress towards completion of the initial public offering process. We assessed that a near-term initial public offering was increasingly likely based upon discussions with our investment bankers and improving market conditions. We entered into a letter of intent with our underwriter in February 2013 and filed our amended registration statement on Form S-1 in February 2013. In December 2012, the state of the initial public offering market was uncertain with few biotechnology companies completing initial public offerings during the year ended December 31, 2012; however, beginning in 2013, initial public offerings for biotechnology companies appeared far more promising. Our consummation of our \$5,000,000 Series B Preferred Stock private placement strengthened our balance sheet, resulting in the elimination of the going concern opinion in our 2012 audit opinion that had appeared in its 2011 audit opinion and had discouraged some investors at that time, and further increasing the likelihood of a successful initial public offering. In addition, we became eligible for an additional \$1,000,000 in debt financing from Square 1 Bank due to the consummation of the Series B financing. The consummation of our Series B Preferred Stock private placement enabled us to initiate development of our HS-110 protocol synopsis, complete process development to enable manufacturing of HS-410 clinical-grade materials for anticipated clinical trials and engage oncology experts to work with us to progress our development efforts. In addition, our lead investigator began preparations for a grant funded clinical trial and our lead scientist published positive findings in the Journal of Immunology. The PWERM is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment

returns, considering each of three future scenarios: an IPO, a sale or merger, or liquidation. The equity is allocated pro rata among the total common shares on as-converted basis. The value per share under each scenario was then probability weighted and the resulting weighted values were summed to determine the fair value per share for each class. Our calculated discounts for the lack of marketability through the use of the Black-Scholes-Option Pricing Model, and applied an implied discount for marketability of 15.4% for the IPO scenario, and 40% for the sale or merger scenario. The expected outcomes were weighted based on a probability of twenty percent (20%) for the liquidation scenario, with a higher probability for an IPO scenario of fifty percent 50.0% and a probability of thirty percent (30.0%) for the sale or merger scenario. The fair values of the equity determined using the IPO and non-IPO scenarios were weighted according to our estimate of the probability of each scenario. Based on the PWERM model, the Board of Directors determined the fair value of our common stock at March 31, 2013 to be \$8.81.

In late May 2013, in consultation with the underwriters, we determined the anticipated initial public offering price range to be \$10.00 to \$12.00 per share. We believe that the difference between the fair value of our common stock for March 31, 2013 and the midpoint of the initial public offering price range of \$11.00 per share is the result of several factors. The midpoint of the initial public offering price range of \$11.00 per share assumed that the initial public offering has occurred and a public market for the common stock has been created, and therefore excludes any marketability or liquidity discount for our common stock, which was taken into account in the March 31, 2013 valuation. In addition, there were differences in valuation methodologies, assumptions and inputs used by the underwriters in their valuation analysis discussed with us compared to the valuation methodologies, assumptions and inputs used by the valuations considered by our board of directors. The underwriters considered a broader range of companies with higher valuations than the comparable companies considered in the valuations reviewed by the board. The underwriters also assessed the state of the capital markets which they felt were favorable. The addition of Cantor Fitzgerald & Co. as a co-manager for the initial public offering further strengthened the likelihood of the consummation of an initial public offering. The consideration of our enhanced technology portfolio, including the entering into of an options agreement with the University of Miami in April 2013, expansion of our senior management team, including retention of a part time Chief Financial Officer in May 2013, and progression of our clinical drug development plan all contributed to the increase in the fair market value of our common stock.

On April 7, 2011, we granted stock options to purchase a total of 12,610 and 108,696 shares at an exercise price of \$0.64 and \$0.71, respectively. We determined that the fair value of the common stock on the date of grant was \$0.64 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2011 that indicated a valuation price of \$0.64 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2011 to April 7, 2011.

On April 12, 2011, we granted stock options to purchase a total of 141,852 shares at an exercise price of \$0.64. We determined that the fair value of the common stock on the date of grant was \$0.64 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2011 that indicated a valuation price of \$0.64 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2011 to April 12, 2011.

On October 25, 2011, we granted stock options to purchase a total of 49,133 shares at an exercise price of \$0.64. We determined that the fair value of the common stock on the date of grant was \$0.64 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2011 that indicated a valuation price of \$0.64 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2011 to October 25, 2011.

On November 22, 2011, we granted stock options to purchase a total of 21,740 shares at an exercise price of \$0.64. We determined that the fair value of the common stock on the date of grant was \$0.64 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2011 that indicated a valuation price of \$0.64 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2011 to November 22, 2011.

On April 25, 2012, we granted stock options to purchase a total of 100,261 shares at an exercise price of \$0.76. We determined that the fair value of the common stock on the date of grant was \$0.76 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2012 that indicated a valuation price of \$0.76 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2012 to April 25, 2012.

On May 30, 2012, we granted stock options to purchase a total of 1,305 shares at an exercise price of \$0.76. We determined that the fair value of the common stock on the date of grant was \$0.76 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2012 that indicated a valuation price of \$0.76 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2012 to May 30, 2012.

On November 8, 2012, we granted stock options to purchase a total of 77,176 shares at an exercise price of \$0.76. We determined that the fair value of the common stock on the date of grant was \$2.23 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of December 31, 2012 that indicated a valuation price of \$2.23 per share.
- that there were no material changes in factors impacting the common stock per share value from November 8, 2012 to December 31, 2012.

On April 29, 2013, we granted stock options to purchase a total of 34,132 shares at an exercise price of \$8.81. We determined that the fair value of the common stock on the date of grant was \$8.81 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2013 that indicated a valuation price of \$8.81 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2013 to April 29, 2013.

On May 15, 2013, we granted stock options to purchase a total of 38,364 shares at an exercise price of \$8.81. We determined that the fair value of the common stock on the date of grant was \$8.81 per share. To assess the reasonableness of our fair value on this date, we considered:

- the independent valuation report of March 31, 2013 that indicated a valuation price of \$8.81 per share; and
- that there were no material changes in factors impacting the common stock per share value from March 31, 2013 to May 15, 2013.

## Aggregate Intrinsic Value of Equity Awards

Based upon an assumed public offering price of \$11.00 per share, the midpoint of the range reflected on the cover page of this prospectus, the aggregate intrinsic value of outstanding vested and unvested stock options as of March 31, 2013 (unaudited) was \$4.7 million and \$1.4 million, respectively.

### Preferred Stock Warrant Liability

We have accounted for our freestanding warrants to purchase our Series A Preferred Stock as liabilities at fair value on the accompanying consolidated balance sheets. Prior hereto the warrants could only be settled in shares of Series A Preferred Stock. The warrants have been subject to re-measurement at each balance sheet date, and the change in fair value, if any, is recognized as other income (expense). At the time of the offering the warrants will have the right to purchase common stock so we will not continue to adjust the liability for changes in fair value.

Significant assumptions used in the valuation of the warrants were as follows:

	March 31, 2013 (Unaudited)	December 31,	
		2012	2011
Exercise price	\$4.83	\$4.83	\$4.83
Risk-free interest rate	1.56% – 1.87%	1.78%	1.65% – 1.92%
Expected volatility	76.2 – 76.3%	75.6 – 76.3%	75.1 – 76.7%
Expected life (years)	10	10	10
Expected dividend yield	0%	0%	0%

### Material Weaknesses in our Internal Control over Financial Reporting.

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.

We have historically 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 consolidated financial statements for the years ended December 31, 2012 and 2011. Our management discovered certain conditions that we deemed to be material weaknesses 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. Regardless, following the completion of this offering 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.

## Results of Operations

### For the Three Months Ended March 31, 2013 and 2012

#### Revenues

We had no revenue for the three months ended March 31, 2013 and March 31, 2012. Historically our revenue has been entirely comprised of grant awards, of which we received none in the three months ended March 31, 2013 and March 31, 2012. We plan to continue our efforts to secure future grant funding to subsidize our ongoing research and developments costs.

#### Operating Expenses

Operating expenses are primarily comprised of research and development expenses and general and administrative expenses. For the three months ended March 31, 2013, research and development expenses represented approximately 57% of operating expenses, clinical trials and regulatory represented approximately 8% of operating expenses, and general and administrative expenses represented approximately 35% of operating expenses. For the three months ended March 31, 2012, research and development expenses represented approximately 38% of operating expenses, clinical trials and research represented approximately 11% of operating expenses, and general and administrative expenses represented approximately 51% of operating expenses. For the three months ended March 31, 2013, total operating expenses increased 74% to \$770,482 from \$443,629 for the three months ended March 31, 2012. Research and development expenses increased approximately 158% to \$440,289 for the three months ended March 31, 2013 from \$170,765 for the three months ended March 31, 2012. For the three months ended March 31, 2013, approximately \$199,500 of the increase in research and development expenses were attributable to manufacturing costs related to our Phase 2 lung cancer trial for a total expense for the project of approximately \$268,000 for the period as compared to approximately \$24,315 incurred for the first quarter of 2012. From inception, we have incurred approximately \$625,750 and \$108,146 in costs for our lung cancer and bladder cancer projects, respectively. Approximately \$18,250 was attributable to three new research projects with a university to further study the use of our *ImPACT* therapy for new oncology and infectious disease indications. The balance of the variance in such expenses were not attributable solely to any one project but were attributable to research relevant to all of our projects. Clinical trials and regulatory expenses increased approximately 33% to \$62,057 for the three months ended March 31, 2013, from \$46,807 for the three months ended March 31, 2012, due to the engagement of an outside consultant to assist in the monitoring of our clinical trials. General and administrative expenses increased approximately 19% to \$268,136 for the three months ended March 31, 2013, from \$226,057 for the three months ended March 31, 2012. Approximately \$27,600 was attributable to the retention of a Director of Finance as well as an increase in risk management costs of \$6,720. Additionally, a new loan was negotiated for short term financing requirements that increased our banking fees by approximately \$7,975.

#### Non-Operating Expenses

Non-Operating Expenses are primarily comprised of interest expense. The interest expense for periods ended March 31, 2013 and March 31, 2012 was \$28,342 and \$1,759 respectively, an increase of \$26,583. This increase was due to interest on proceeds drawn against a note payable not executed until August of 2012.

#### Net Loss

Our net loss after deducting the non-controlling interest increased 73% to \$763,856 for the three months ended March 31, 2013 from \$441,684 for the three months ended March 31, 2012 for the reasons cited above.

### For Years Ended December 31, 2012 and 2011

#### Revenues

Total revenue for the twelve months ended December 31, 2012, decreased approximately 98% to \$3,110 as compared to \$187,787 for the twelve months ended December 31, 2011. For both periods our revenue was entirely comprised of grant awards. In October 2010, we were awarded a grant from the Internal Revenue Service of \$244,479 for the reimbursement of qualified investments in a therapeutic discovery project under section 48 of the Internal Revenue Service Code. The grant proceeds were paid in two installments of which \$162,435 was paid in 2011 and was included in revenue for the twelve months ended December 31, 2011. We plan to continue our efforts to secure future grant funding to subsidize our ongoing research and developments costs.



### *Operating Expenses*

Operating expenses are primarily comprised of research and development expenses and general and administrative expenses. For the twelve months ended December 31, 2012, research and development expenses represented approximately 38% of operating expenses, clinical trials and regulatory represented approximately 11% of operating expenses, and general and administrative expenses represented approximately 51% of operating expenses. For the twelve months ended December 31, 2011, research and development expenses represented approximately 56% of operating expenses, clinical trials and research represented approximately 11% of operating expenses, and general and administrative expenses represented approximately 33% of operating expenses. For the twelve months ended December 31, 2012, total operating expenses increased 5.5% to \$2,345,787 from \$2,222,587 for the twelve months ended December 31, 2011. Research and development expenses decreased approximately 28% to \$902,938 for the twelve months ended December 31, 2012 from \$1,246,587 for the twelve months ended December 31, 2011. This decline was due to expenses of approximately \$162,000 for a large research project and approximately \$146,000 for past patent expenses to the University of Miami which were incurred during 2011. For the twelve months ended December 31, 2012, approximately \$357,744 and \$108,147 of the research and development expenses were attributable solely to research related to our lung cancer and bladder cancer projects, respectively, and the balance of such expenses were not attributable solely to any one project but were attributable to research relevant to all of our projects. Comparatively, for the twelve months ended December 31, 2011 there were no such research expenditures that benefited any one project specifically. Also, research and development manufacturing costs decreased by approximately \$101,000 as manufacturing was being phased into the clinical and regulatory phase. Clinical trials and regulatory expenses decreased approximately .08% to \$253,189 for the twelve months ended December 31, 2012, from \$255,210 for the twelve months ended December 31, 2011, which is consistent between the two periods. General and administrative expenses increased approximately 65% to \$1,189,660 for the twelve months ended December 31, 2012, from \$720,790 for the twelve months ended December 31, 2011, primarily as a result of our decision to retain a full-time CEO in the second quarter of 2011 which resulted in additional expense of \$200,450. Additionally, we incurred additional expenses of \$72,723 for a contracted and full-time accounting staff. Finally, during the twelve months ended December 31, 2012 we incurred additional insurance expenses of \$13,348 associated with enhanced risk management such as Directors and Officers Insurance and additional liability coverage, additional rent expense and administrative expenses of \$31,641 due primarily to the execution of a new lease, additional stock compensation expense of approximately \$138,350, additional financing costs of approximately \$38,000, and additional audit fees of approximately \$24,000. The additional unspecified increase in the general and administrative expense was attributable to our expansion.

### *Non-Operating Expenses*

Non-Operating Expenses was primarily comprised of interest expense from our convertible notes and the 2012 write off of the debt discount associated with debt paid off during the period which increased to \$101,086 for the year ended December 31, 2012 from \$63,173 for the year ended December 31, 2011.

### *Net Loss*

Our net loss after deducting the non-controlling interest increased 15% to \$2,420,200 for the year ended December 31, 2012 from \$2,104,884 for the year ended December 31, 2011. Although research and development costs declined by 28% due to decreased patent expenditures, the maturation of the company required additional staffing. A Vice President of Clinical and Regulatory was hired to manage our clinical trials as well as a full time Director of Finance. Additionally, the salary of the CEO was increased as stipulated in his employment agreement.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through proceeds from equity financings and debt financings, primarily involving private sales of our common stock and other debt and equity securities, and to a lesser extent from the proceeds from grant awards and commitments from banks and vendors.

In March 2013, we closed the first tranche of our Series B Preferred Stock private placement offering in which we sold an aggregate of 1,891,419 shares of our Series B-1 Preferred Stock for gross proceeds of \$5,050,090.

Our cash and cash equivalents totaled \$4,889,723 as of March 31, 2013, an increase of \$4,837,795 from March 31, 2012. The primary source of cash during the quarter ended March 31, 2013 was the issuance in March of 1,891,419 shares of our Series B-1 Preferred Stock for gross proceeds of \$5,050,090. Our cash and cash equivalents totaled \$5,030 as of December 31, 2012, a decrease of \$93,616 from December 31, 2011. During the year ended December 31, 2012, the primary sources of cash were issuances of stock and the draw downs on Square 1's promissory notes. In 2012, \$725,000 was drawn on the Square 1 promissory notes and the outstanding principal balance at December 31, 2012 was \$725,000. As of May 1, 2013, the Company has outstanding \$725,000 on the promissory notes, with \$2,275,000 available for future use. The Tranche A Loan principal balance is \$500,000, the interest rate is currently at 6%, and the maturity date is August 7, 2016. The Term Loan B principal balance is \$225,000, the interest rate is 4.25%, and the maturity date is December 14, 2014. The primary use of cash during the year ended December 31, 2011 was for working capital requirements.

Since inception we have raised \$2,623,709 from the issuance of convertible notes to investors, of which notes in the principal amount of \$2,273,709 were issued to one investor, Brightline Ventures III, LLC, the managing member of which is Mr. Smith, a member of our Board. As of December 31, 2010, we had notes outstanding to three investors in the aggregate principal amount of \$1,176,000. The notes accrued interest at a rate of 3% per annum and were scheduled to mature 18 months after issuance. In 2011, we raised an additional \$1,447,709 from the issuance of notes to three investors, one of which was Brightline Ventures III, LLC. The notes accrued interest at a rate of 3% per annum and were scheduled to mature 18 months after issuance. All of the notes were converted into shares of Series A Preferred Stock in September 2011.

Our continued operations will primarily depend on our ability to raise additional capital from various sources, including equity and debt financings, as well as grants and bank financings. On October 20, 2011, we entered into an agreement with a vendor that allowed us to make up to \$950,000 of payments for invoiced services rendered by such vendor through the issuance of a convertible note. In May 2013, the note with the vendor was extinguished and the vendor extended the due date of all payables owed, including amounts previously due under the Note, until the earlier of July 15, 2013 or this offering or any other financing in which we receive gross proceeds of \$2,500,000. If the closing of such financing does not occur prior to July 15, 2013 then one half of the payables owed as of July 15, 2013 shall be due July 15 2013 and the balance shall remain payable until such a financing is consummated. On December 14, 2011, we entered into a promissory note with the North Carolina Biotechnology Center pursuant to which we could borrow up to \$250,000. The note accrued interest at a rate of 4.25% per annum. The principal was payable in annual installments in the amount of five percent (5%) of the outstanding principal as of the date of such payment, commencing on the anniversary date of the related loan agreement and continuing annually on the same day of each calendar period thereafter until December 13, 2014. In August 2012, we repaid all amounts outstanding under the note from the proceeds of the Square 1 Bank loan described below. In connection with the loan from North Carolina Biotechnology Center, we issued the North Carolina Biotechnology Center a warrant exercisable for 12,940 shares of our common stock at an exercise price of \$4.83 per share, which warrant expires on December 13, 2021. In August 2012, we entered into a secured loan with Square 1 Bank, the proceeds of which were used in part to pay off the loan from North Carolina Biotechnology Center. The loan and security agreement that we entered with Square 1 Bank in connection with the secured loan (the "Square 1 Agreement") provides that Square 1 Bank will provide us with a term loan in the aggregate principal amount not to exceed \$1,000,000 to be used for working capital and capital expenditures (the "Tranche A Loan"). The Tranche A Loan will be available to us until August 7, 2013. The Tranche A Loan is payable on August 7, 2013 in 36 monthly installments of principal and accrued interest. The Tranche A Loan matures on August 7, 2016. If we receive a grant that provides aggregate funds with a value of \$16,000,000, the maximum aggregate of the Tranche A Loan and the Tranche B Loan amount increases to \$2,775,000. Both the Tranche A Loan and the Tranche B Loan accrue interest monthly at an interest rate of 3% plus prime or 6% per annum whichever is greater. The Square 1 Agreement, as amended, also provides that if we receive at least \$4,500,000 from the sale of our equity to investors after February 15, 2013 but on or before March 31, 2013 (such date we receive such funds being referred to as the "Trigger Date"), we can borrow an additional term loan in the aggregate principal amount not to exceed \$1,000,000 to be used for working capital and capital expenditures (the "Tranche B Loan"). Due to the closing of the Series B-1 Preferred Stock private placement in March 2013, we will be able to borrow an additional \$1,000,000 under such loan. The Tranche B Loan is payable as interest-only prior to the twelve month anniversary of the Trigger Date month after until August 7, 2013 and thereafter is payable in equal monthly installments of principal plus accrued interest until August 7, 2016. The Tranche B Loan matures on August 7, 2016. Square 1 Bank also made one term loan in the amount of \$225,000, which was used to repay our debt to North Carolina Biotechnology Center (the "Term B Loan"). The Term B Loan matures December 14, 2014 and requires payments on the one and two year anniversary of the date of issuance equal to five percent of the principal amount of the loan plus accrued interest, with the balance of the loan being paid on maturity. The Term B Loan accrues interest monthly at an interest rate of 4.25% per annum. Once repaid the loans may not be re-borrowed. The loans are secured by a lien on substantially all of our assets, including our stock in our subsidiaries

but excluding our intellectual property. Finally, Square 1 Bank also made one Non-Formula Advance (the "Non-Formula Advance") in the aggregate principal amount of \$200,000 which is payable as interest-only on the 5<sup>th</sup> calendar day of each month through January 9, 2014 when the entire principal amount is due. As of May 1, 2013, we had outstanding \$725,000 under the Square 1 Bank loans. In connection with the loan, we issued Square 1 Bank a warrant, as amended, exercisable for 17,500 shares of our common stock which after adjustment for our 1-for-2.3 stock split will be convertible into 7,609 shares of common stock. The warrant is exercisable for ten years at a price of \$4.83, which price is subject to adjustment for certain transactions including certain dilutive transactions. The warrant holder is entitled to piggyback registration rights with respect to the underlying shares.

The loan and security agreement with Square 1 Bank sets forth various affirmative and negative covenants that the Company must comply with, including covenants regarding financial reporting, and "cash maintenance" burn requirements, incurrence of indebtedness and mergers and acquisitions. We plan to use approximately \$300,000 of the proceeds of this offering to repay the portion of the loans from Square 1 Bank due over the 12 months beginning September 2013. We currently have: (i) \$500,000 outstanding under the Tranche A Loan and under the terms of the loan we are required to pay the principal balance plus accrued interest in 36 monthly installments beginning September 7, 2013 and ending August 7, 2016 and (ii) \$225,000 outstanding under the Term Loan B, and under the terms of the loan we are required to make payments of 5% of the outstanding principal balance plus accrued interest each on August 2013 and 2014, with the remaining principal balance, plus all accrued interest, due December 14, 2014. In 2013, we borrowed \$200,000 under the Non-Formula Advance from Square 1 Bank which was repaid in full in 2013 and \$200,000 cannot be reborrowed.

In April 2010, we were awarded a grant award from the National Institute of Health in the amount of \$300,000, of which \$248,648 was paid to us in 2011. In October 2010, we were awarded a grant from the Internal Revenue Service of \$244,479, of which \$162,435 was paid in 2011.

#### **Current and Future Financing Needs**

We have incurred an accumulated deficit of approximately \$6,699,138 as of March 31, 2013. We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

The actual amount of funds we will need to complete our 125 patient Phase 2 trial on patients with advanced non-small cell lung cancer and a 93 patient, Phase 1/2 trial of HS-410, in bladder cancer which is estimated to be \$9,350,000, is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the progress and cost of our research and development activities;
- the number and scope of our research and development programs;
- the progress and cost of our preclinical and clinical development activities;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

We have based our estimate on assumptions that may prove to be wrong. We continue to require additional funds to fully implement our planned research and development and may need to obtain these funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include corporate partnerships or public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time other than as described previously and there can be no assurance given that any additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our

existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and, as a result, our business, financial condition and results of operations would be materially harmed.

#### License and Contractual Obligations

Below is a table of our contractual obligations for the years 2013 through 2017 and thereafter through December 31, 2022 (in thousands):

	Year ended December 31,					Thereafter	Total
	2013	2014	2015	2016	2017		
Total License Agreements(1)	\$ 30	\$ 30	\$ 30	\$ 30	\$ 280	\$ 150	\$ 550
Lease Agreements(2)	28	—	—	—	—	—	28
Total	\$ 58	\$ 30	\$ 30	\$ 30	\$ 280	\$ 150	\$ 578

(1) Represents minimum royalty payment commitments under our license agreements that are required to be paid with the passage of time.

(2) In November 2011, we entered into a thirteen month lease agreement for office space commencing February 1, 2012 for a monthly rent of \$3,870. The lease term may be extended for an additional 24 months on substantially the same terms. On December 19, 2012, we entered into a lease modification agreement which extended the lease term until July 31, 2013 and the monthly rent increased to \$4,046. Future minimum lease payments are as set forth above.

Below is a table of our contractual payments under the Company's notes payable and convertible notes payable agreements for the years 2013 through 2016 as of May 21, 2013 (in thousands):

	Year ended December 31,				Total
	2013	2014	2015	2016	
Notes Payable	\$ 104	\$ 403	\$ 178	\$ 113	\$ 798
Convertible Notes Payable*	694	—	—	—	694
Total	\$ 798	\$ 403	\$ 178	\$ 113	\$ 1,492

\* In May 2013, the convertible note payable was extinguished and the vendor extended the due date of all payables owed, including amounts previously due under the note, until the earlier of July 15, 2013 or this offering or any other financing in which we receive gross proceeds of \$2,500,000. If the closing of such financing does not occur prior to July 15, 2013 then one half of the payables owed as of July 15, 2013 shall be due July 15 2013 and the balance shall remain payable until such a financing is consummated.

## 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*<sup>™</sup> 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 of goods benefits compared to autologous patient-specific approaches.

Our most advanced product candidates are HS-110 and HS-410.

### HS-110

We have submitted an IND to initiate a Phase 2 clinical trial in non-small cell lung cancer (NSCLC) patients with our therapeutic vaccine candidate HS-110, which is derived from a human lung cancer cell line. HS-110 is a biologic product which consists of a lung cancer cell line that has been genetically modified using our *ImPACT* technology platform to secrete a wide range of lung cancer associated antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient’s cancer. The inventor of the *ImPACT* technology that we license recently reported results from a Phase 1 open-label, single center clinical trial of HS-110 in patients with advanced NSCLC. We believe the results provide clinical evidence that HS-110 is capable of generating anti-cancer immune responses. Eighteen patients were vaccinated, and 15 of the 18 vaccinated patients completed the first course of three planned courses of therapy. Two patients completed all three planned courses of therapy.

HS-110 showed no overt toxicity. There were no serious adverse events (SAEs) that were considered by the trial investigator to be treatment-related. Most of the adverse events (AEs) were reported as mild or moderate (grade 1 or 2) with the most frequent being skin induration and rash that were transitory and usually resolved in 1 to 2 weeks. HS-110 provides evidence of a CD8-CTL IFN- $\gamma$  immune response in patients with advanced NSCLC. In 11 of the 15 patients (73%) that completed the first course of therapy with HS-110, there was a twofold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN- $\gamma$ ). These patients also exhibited an estimated median survival of 16.5 months (95% CI:7.1-20.0). In contrast, 4 patients were immune non-responders and survived 2.1, 2.3, 6.7, and 6.7 months, or a median survival of 4.5 months, which is consistent with the expected survival times in this patient population. The protocol required that we look for such responses, but, as is typical in immunotherapy, no partial or complete tumor responses were observed. The median one-year overall survival rate of patients in the study was 44% (95% CI:21.6-65.1), comparing favorably to a 5.5% rate based on published data from a 43-patient advanced lung cancer population. One of the late-stage lung cancer patients is surviving over four years since starting the therapy and another patient is surviving over three years since starting the therapy. These findings were consistent with multiple pre-clinical published studies on *ImPACT* therapy.

### HS-410

We intend to submit an IND to initiate a Phase 1/2 bladder cancer trial with HS-410, which is derived from a human bladder cancer cell line. HS-410 is a biologic product which consists of a bladder cancer cell line which has been genetically modified using our *ImPACT* technology platform to secrete a wide range of bladder cancer antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient’s bladder cancer. Following FDA clearance, we intend to initiate a 93 patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 6 weekly intravesical bacillus Calmet-Guerin (BCG) immunotherapy installations. We anticipate including approximately 8-10 clinical sites with an enrollment period of 12-18 months. Patient enrollment is expected to begin in Q3-2013.

**Additional Indications**

We are also developing *ImPACT* therapeutic vaccines for breast cancer and ovarian cancer. The inventor of the *ImPACT* technology intends to initiate a second grant-funded, investigator-sponsored Phase 1/2 clinical trial of our *ImPACT* therapy in conjunction with other therapies against NSCLC in the third quarter of 2013. To date, in excess of \$14,000,000 of funding has been awarded to the primary inventor of the technology we license by the National Institutes of Health (NIH) and through other research and clinical grants, which has been used to further develop our *ImPACT* technology platform that 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 inventors 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. The NIH is also currently fully funding the primary inventor’s study of an HS-HIV product candidate in non-human primates with a therapeutic and prophylactic vaccine for the treatment and prevention of HIV utilizing the *ImPACT* approach.

The table below summarizes our current product candidates and their stages of development:

Product Candidate	Indication	Phase of Development	Upcoming Milestone(s)
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Open commercial IND	2013 - Initiate Phase 2
HS-410	Bladder Cancer Adjuvant	IND submission planned. Completing cGMP Drug Manufacturing	2013 - Initiate Phase 1/2
HS-310	Ovarian Cancer	Pre-clinical. Initiating cGMP Drug Manufacturing	2014 - Phase 1/2 trials
HS-510	Triple Negative Breast Cancer (TNBC)	Pre-clinical. Cell line development underway	2014 - Phase 1/2 trials

The table below summarizes the primary inventor’s clinical development of the *ImPACT* technology:

Product Candidate	Indication	Phase of Development
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Completed Phase 1 Interim Study Report
HS-110	Non-Small Cell Lung Cancer (NSCLC) Combination Therapy	Completed cGMP Drug Manufacturing. 2013 - Initiate Phase 1/2
HS-HIV	HIV	Pre-clinical. NIH-sponsored Primate Studies Completed

***ImPACT* Therapy—Novel Pan-Antigen Immune Activation**

Our *ImPACT* therapy is a novel technology platform designed to educate and stimulate the immune system to combat specific disease targets, such as cancer cells. *ImPACT* utilizes live attenuated, human-derived, genetically-modified cells to generate an array of tumor associated antigens and secrete an essential immunostimulatory protein called “gp96-Ig”. The secreted proteins are designed to generate an immune response against cancer cells by mobilizing and activating a patient’s own killer T cells to target a broad array of different tumor antigens with the goal of eliminating cancer cells. In contrast with other vaccine technologies that target only one antigen, *ImPACT*’s pan-antigen approach which may enable the body to induce and maintain an immune response against a broad array of tumor-specific proteins, by potentially providing a more robust and sustained immune response and limiting cancer cells’ ability to evade the immune system. We believe the clinical and pre-clinical results suggest that *ImPACT* generates anti-tumor immune responses capable of targeting and destroying tumors. We believe our novel, off-the-shelf, live cell therapy has the potential to be used to not only combat a wide range of cancers, but also against various infectious diseases, such as hepatitis C, malaria and HIV, for which non-human primate studies, which we believe are encouraging, have been completed. We have leveraged our existing infrastructure by developing additional product candidates in areas where we can use our proprietary technology. Our success will

depend on the clinical and regulatory success of our product candidates and our ability to retain, on commercially reasonable terms, financial and managerial resources, which are currently limited. To date, we have not received regulatory approval for any of our product candidates or derived any revenues from their sales. Moreover, there can be no assurance that we will ever receive regulatory approval for any of our product candidates or derive any revenues from their sales. We should have sufficient capital from the offering to operate the company for 24-30 months.

#### ***Our ImPACT Therapy Product Candidates***

We plan to submit our Phase 2 clinical trial protocol for HS-110, our lead drug candidate, against non-small cell lung cancer (NSCLC) to FDA and initiate the trial in 2H-2013. Our Phase 2 trial will expand upon the Phase 1 results obtained by the primary inventor as described below.

We also plan to initiate a Phase 1/2 clinical trial against bladder cancer in Q3-2013 using our HS-410 drug candidate. We plan to utilize this vaccine to delay or prevent the recurrence of bladder cancer in post-resected bladder cancer patients.

We are also anticipating initiating clinical trials using our *ImPACT*-based product candidates against a number of other diseases, including ovarian cancer and breast cancer.

#### ***Our Product Candidates and Clinical Development Programs***

Our development program involves testing our *ImPACT*-based product candidates against a number of disease targets, including non-small cell lung cancer, breast cancer, ovarian cancer, bladder cancer and HIV. We are planning to enter a Phase 2 clinical trial with our first therapeutic vaccine, HS-110, for non-small cell lung cancer (NSCLC) in 2H-2013. We are also planning to initiate a Phase 1/2 clinical trial of HS-410 for bladder cancer in Q3-2013. In addition, we may also initiate Phase 1 clinical trials for breast and/or ovarian cancer in 2014, dependent upon the receipt of additional non-dilutive grants and/or product financings. The primary inventor of the technology that we license is conducting a study in non-human primates with a therapeutic and prophylactic vaccine for the treatment and prevention of HIV. This ongoing study is fully funded by the NIH.

#### **Strengths and Competitive Advantages**

- We believe our *ImPACT* technology combines broad antigen targeting of known and unknown tumor associated antigens complexed with a potent immune adjuvant. We believe *ImPACT* has been shown to activate the immune system against a wide variety of antigens by eliciting a significant cytotoxic T cell immune response as measured by extensive pre-clinical and initial clinical immunological testing. The activated immune response generated by our *ImPACT* Therapy may be useful in treating a wide range of cancers and infectious diseases.
- We have submitted an IND and intend to initiate a Phase 2 clinical trial in NSCLC patients with our therapeutic vaccine candidate HS-110, which is derived from a genetically-modified human lung cancer cell line. We expect to initiate a Phase 1/2 clinical trial for bladder cancer with our second product candidate, HS-410, in 2H-2013.
- The National Institute of Health (NIH) and other organizations have provided funding to the primary inventor of the technology that we license for both his pre-clinical and clinical studies.
- Our proprietary *ImPACT* technology platform is being applied to develop multiple therapeutic vaccines against a wide range of cancers and infectious diseases. Generating positive results and gaining FDA approval for multiple therapies would lower our dependence on any one drug in order to generate returns.
- We believe our therapeutic vaccines are easier and less expensive to manufacture than autologous vaccines because our therapeutic vaccines do not require the harvesting of blood and/or tumor tissue from each patient in order to manufacture a course of treatment. We believe this is highly advantageous because it can bring the logistics, manufacturing, cost and distribution of our therapeutic vaccines within the purview of traditional biopharmaceutical product channels and dramatically expand our pool of corporate partners.

- We believe that we may be able to rapidly develop new allogeneic vaccines for different types of cancers and other diseases as our technology can readily be applied to many different forms of cancer.
- Our therapies do not require an additional adjuvant. Some vaccines require the addition of another drug, called an adjuvant, to enhance their effectiveness. Adjuvants typically cause irritation at the injection site. HS-110, one of our product candidates, is itself an adjuvant, so we do not have to use additional adjuvants to generate and maintain an activated immune response, thereby limiting any injection site reaction to that caused by our own therapies.
- We believe our business model is capital efficient as we continue to leverage academic and institutional resources in order to develop new products and to begin to move these products into and through clinical trials.

## Strategy

Our objective is to become a leading biopharmaceutical company specializing in the development and commercialization of allogeneic, off-the-shelf therapeutic vaccines. We are focused on discovering, developing and applying our core platform *ImPACT* technology towards a number of disease indications. The key elements of our strategy are:

- *Develop and obtain regulatory approval for our ImPACT-based products.* We plan to initiate a Phase 2 clinical trial in NSCLC in 2H-2013 and intend to conduct a Phase 1/2 clinical trial in bladder cancer in Q3-2013. Additionally, we plan to initiate clinical trials against breast and ovarian cancer in 2014, pursuant to receiving additional non-dilutive grants and/or product financings. After NSCLC, bladder, breast and ovarian cancers, we plan to initiate additional clinical trials against other disease targets utilizing our *ImPACT* technology platform.
- *Maximize commercial opportunity for our ImPACT technology.* Our product candidates target large markets with significant unmet medical needs. For each of our product candidates, we seek to retain all manufacturing, marketing and distribution rights which should give us the ability to maximize the economic potential of any future U.S. or international corporate partnerships. We believe that we should be well positioned to successfully commercialize our product candidates independently or through U.S. and international corporate partnerships.
- *Further expand our broad patent portfolio.* We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to do so. We have obtained exclusive rights to five different patent families directed to therapeutic compositions and methods related to our vaccine platform and preclinical development programs for cancer. These families comprise five PCT applications, six issued patents, two allowed or accepted patent applications, and thirty-seven pending patent applications. These patents and applications cover the United States, Europe, and Japan as well as several other countries having commercially significant markets.
- *Manage our business with efficiency and discipline.* We believe we have efficiently utilized our capital and human resources to develop and acquire our product candidates and programs, and create a broad intellectual property portfolio. We operate cross-functionally and are led by an experienced management team with backgrounds in developing and commercializing product candidates. We use project management techniques to assist us in making disciplined strategic program decisions and to attempt to limit the risk profile of our product pipeline.
- *Obtain additional grant funding.* To more fully develop our *ImPACT* technology platform and its application to a variety of human diseases, we plan to continue to seek and access external sources of grant funding on our own behalf and in conjunction with our academic partners to support the development of our pipeline programs. While we intend to work with our academic partners to secure additional grant funding, these partners have no obligation to work with us to secure such funding. We also intend to continue to evaluate opportunities and, as appropriate, acquire or license technologies that meet our business objectives.



· *Continue to both leverage and fortify our intellectual property portfolio.* We believe that we have a strong intellectual property position relating to the development and commercialization of our *ImPACT* technology platform. We plan to continue to leverage this portfolio to create value. In addition to fortifying our existing intellectual property position, we intend to file new patent applications, in-license new intellectual property and take other steps to strengthen, leverage, and expand our intellectual property position.

### ***Disease Targets and Markets***

#### **The Oncology Market**

The American Cancer Society estimates that 1.66 million people in the U.S. will be diagnosed with cancer in 2013. The lifetime probability of being diagnosed with an invasive cancer is 45% for men and 38% for women. It is projected that 580,350 Americans will die from cancer in 2013.

Despite continuous advances made in the field of cancer research every year, there remains a significant unmet medical need as the overall five-year survival rate for cancer patients diagnosed between 2001 and 2007 is an average of 67%. According to the Center of Disease Control, in 2011, cancer was the second leading cause of mortality in the U.S. (23.2%) behind heart disease (24.1%). The American Cancer Society estimates that one in four deaths in the U.S. is due to cancer.

The main treatments for cancer are surgery, radiotherapy and chemotherapy. There are often, however, significant debilitating effects resulting from these treatments or lingering morbidity associated with these approaches to treatment of cancer. Our goal is to develop compounds that can lengthen survival times and improve the quality of life of cancer patients and survivors.

Although there are a large number of patients, treatment and management of cancer is performed by a relatively concentrated pool of medical professionals. We plan to reach this prescriber base using a relatively small commercial infrastructure that we intend to develop in the future by either hiring internally, partnering or contracting with one or more third-party entities with an established sales force. These development plans are dependent on our raising additional capital, the success of HS-110, HS-310, HS-410 and HS-510 and any technologies we might develop in the future and successful negotiation of commercial relationships, none of which we have completed to date. We believe, however, assuming the efficacy and safety of HS-110 and any other technology we might acquire, that our experienced management team will raise the capital and establish the commercial relationships necessary for success.

#### **Limitations of Current Cancer Therapies**

We believe current cancer treatment alternatives suffer from a number of limitations that impair their effectiveness in improving patient survival and overall quality of life including:

- *Toxicity.* Chemotherapeutic agents are highly toxic to the human body and very often cause a variety of significant and debilitating side effects, including, but not limited to, nausea and vomiting, bleeding, anemia and mucositis. Some targeted therapeutics have fewer systemic toxicities, but still typically have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These side effects limit a patient's ability to tolerate treatment and as such can deprive the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once they become aware of the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, many patients diagnosed with terminal cancer choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer also often cannot tolerate cancer therapy, and certain therapies can hasten death as the patient's health further deteriorates from the therapy applied.
- *Mechanism of action.* While many current therapeutic approaches can be effective against specific targeted cells, the efficacy of these therapies in treating cancer over the long term generally is limited by the abundance and diversity of the cancer and tumor cells, which are believed to enable the targeted cells to adapt and become resistant to the current therapeutic approach over time.

- *Short-term approach.* Other than tumor removal in a surgical procedure, curing the cancer is often not the intent or a potential outcome of many current cancer therapies. Rather, increased survival time is the primary focus of many currently marketed and development-stage cancer therapeutics. In this regard, many cancer therapies show only a modest impact on the overall survival of the patients and only affect the length of time that passes after treatment begins and before the patient's disease worsens or the patient dies.
- *Immune system suppression.* A weakened immune system not only inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases. Current approaches to cancer treatment generally involve introduction of an agent, such as a chemical, an antibody or radiation, which causes cell apoptosis (programmed cell death) or inhibits the proliferation of all cells, including immune cells, which has the unintended consequence of indirectly suppressing the immune system.

## **Immunotherapy Overview**

Our *ImPACT* technology is a form of immunotherapy. Immunotherapy involves administration of a therapeutic agent that enlists or boosts a subject's immune system in order to fight disease.

Commonly recognized successful examples of immunotherapy include *prophylactic vaccines*, such as, childhood immunizations against infectious diseases such as measles, mumps, and rubella. In these cases, usually weakened (attenuated) or inactivated viruses are injected into the body to educate certain immune system cells to recognize and remember small pieces of viral or bacterial proteins (antigens). If and when an individual is subsequently exposed to this same pathogen, the immune system will recognize these antigens immediately and mount a potent immune response to neutralize and eliminate the pathogenic threat.

*Therapeutic vaccines*, such as *ImPACT*-based product candidates, operate in a fashion similar to *prophylactic vaccines* except that *therapeutic vaccines* are administered after a particular disease is already present. In each case, the human immune system is educated and harnessed to recognize and fight the disease of interest. Cancer can be considered a failure of the immune system to effectively recognize and eliminate inappropriately dividing and multiplying (malignant) cells. Under ordinary circumstances the human immune system continuously monitors and eliminates inappropriately dividing cells. However, for reasons that are not entirely understood, under cancerous conditions the immune system fails to recognize malignant cells and such cells are permitted to inappropriately multiply, grow and metastasize to form tumors which eventually become life threatening. Our therapeutic vaccines are designed to assist the immune system in identifying and eliminating malignant cells. Our approach involves the introduction of cellular antigens that are characteristic of malignant cells with the goal of generating an immune response against the particular form of cancer. In our approach, in addition to introducing a number of cancer-specific antigens, we also introduce a protein known as gp96 which stimulates and primes the immune system to further recognize cancer antigens and generates a potent and broad pan-antigen immune response against cancerous cells.

### ***Immunotherapy Approaches***

Immunotherapy is designed to stimulate and enhance the body's natural mechanism for killing cancer cells and virus-infected cells. Generally, immunotherapeutic approaches to treat disease can be separated into two distinct classes, passive and active, based on their mechanism of action.

*Passive Immunotherapy:* Passive immunotherapies generally consist of monoclonal antibodies directed at a single disease-specific enzyme or protein on the surface of the targeted cells with the goal of either killing the targeted cells or preventing them from dividing. Rather than stimulate or otherwise use the body's immune system to initiate the attack on the disease, the attack is made by the therapy which is produced *ex vivo*, or outside of the body. These therapies also are not usually personalized for the patient.

*Active Immunotherapy:* Active immunotherapies generally consist of therapies intended to trigger or stimulate the body's own immune system to fight disease. Active immunotherapies have no direct therapeutic action but rather contain antigens specifically designed to activate the patient's own immune system to find and kill the targeted cells that carry the same antigen. Active immunotherapies depend on the patient's immune system to seek out and destroy targeted cells or tumors. Most active immunotherapies utilize off-the-shelf antigens, known as "defined" antigens, rather than individualized, patient specific antigens, and are often paired with adjuvants, which are agents that generally activate the immune system cells to increase immune response.

*Shortcomings of Immunotherapies:* Both passive and active immunotherapy approaches have shortcomings, which include:

- Most active immunotherapies use normal, non-mutated, self-antigens which are typically poor at stimulating immune responses, even from healthy immune systems. In fact, the human immune system generally does not generate immune responses against self-antigens. Most passive and active immunotherapies also target one or only a few antigens, which increases the probability that infected cells will escape detection by the immune system and immunotherapy.
- Most active immunotherapies employ defined antigens that are not effective against multiple types of cancer.
- Most immunotherapies produce toxic effects resulting in damage to healthy tissues if the target antigen is absorbed by normal cells in addition to the targeted cancer or virus-infected cells.
- Many patients may not be able to mount effective immune responses with immunotherapy due to tumor or virus induced immunosuppression of accessory cells such as CD4+ helper T cells, which are necessary for the immunotherapies to be effective but may be functionally impaired by the patient's disease.
- It can be difficult to commercialize immunotherapies based on cells derived from individual patients in a cost-effective manner as a result of the added complexity, limited patient material for production of multiple doses, and the need to store and ship the individual doses.
- Immunotherapies that rely on defined, off-the-shelf antigens or a single targeted antigen may have limited effectiveness because even within the same type of cancer, the genetic makeup and distinct antigens of a tumor can vary significantly from patient to patient.

These shortcomings were highlighted by the findings of a study recently published in *Nature Medicine* (Finak and Park (2008), Stromal gene expression predicts clinical outcome in breast cancer, *Nature Medicine*, 14, 518 – 527) where the whole genomes of 50 patients' breast cancer tumors were sequenced alongside matching DNA from the same patients' healthy cells to identify the genetic alterations present in the cancerous cells. The study found that the genomic pattern of each of the tumors varied significantly. Of the approximately 1,700 gene mutations found in total, most were specific and unique to the individual patients' cancerous tumors, and that only three of the genetic mutations occurred in 10% or more of the patients.

Although many of the immunotherapies currently in clinical development have shown promising results, we do not believe that any of them utilizes a technology that employs the patient's own cancer or virus-infected cells to create a fully personalized immunotherapy that is directly targeted to the patient's unique genetic disease.

***Our Solution: ImPACT Therapy***

We believe our *ImPACT* Therapy has a number of advantages over existing therapies. These advantages, elaborated below, may enable us to develop commercial products that extend the survival of, and improve the quality of life for, cancer patients:

- It is designed to fight cancer by activating the immune system against a wide variety of cancer antigens.
- It is intended to continually secrete a wide variety of cancer-associated antigens, thus initiating a broad and sustained pan-antigen cytotoxic T cell attack against the targeted cancer. We believe this broad-based attack increases the probability of destroying the targeted cancer.
- It is designed to stimulate a natural immune response against specific cancer cells. We believe this may limit serious adverse events related to treatment.
- We believe that the novel mechanism of action, good tolerability and favorable safety profile will enable our *ImPACT* product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies. We believe our *ImPACT* technology can be targeted to additional specific tumor types by modifying cells from the cancer type of interest.

- Our *ImPACT* Therapy represents a first-in-class adjuvant that functions as both an immune activator and an antigen-delivery vehicle. *ImPACT* is the only adjuvant technology platform currently known to us in clinical development that is specific to CD8+ cytotoxic T cell immune response, which is especially important for developing therapeutics in oncology as well as a number of other infectious disease indications.
- We believe many patients who are too ill to tolerate chemotherapy due to the associated toxicities may be able to benefit from our *ImPACT* product candidates.

## ***ImPACT TECHNOLOGY PLATFORM***

### ***ImPACT Background***

Our *ImPACT* technology represents an allogenic or “off-the-shelf” method to deliver cancer antigens accompanied by heat shock proteins, or HSPs, to illicit an immune response. HSPs are used as a signaling mechanism by the immune system to identify mutated proteins (“antigens”), including those from tumor cells. Although always present within certain cells, HSPs are normally only released when cells die by necrosis or unnatural cell death (rather than apoptosis or natural programmed cell death) and upon release are recognized by the host’s immune system. When a cell dies an unnatural death through a process called “necrosis”, such as when it is infected and killed by a flu virus or other pathogen, the cell releases its contents into circulation setting off a molecular warning to the immune system thereby generating a rapid and potent immune response. Because HSPs very rarely leave cells, the immune system has evolved to recognize HSPs that have been released from dying cells as the sentries of a molecular alarm system. Upon detection of HSPs, the immune system then directs an immune response against any foreign (pathogenic) proteins bound to the HSP at the time the cell that released it died.

HSP’s have several functions including:

- Protecting tissues from pathogens by activating the immune system.
- Acting as a chaperone to:
  - o Facilitate proper protein folding within the endoplasmic reticulum.
  - o Enable proper function of toll-like receptors and the innate immune system.
  - o Carry irreparable proteins to intracellular garbage disposals to be degraded into peptides (short chains of amino acids – protein fragments).
- Loading peptides onto another class of proteins known as MHC I molecules. MHC I molecules move to the cellular surface where they are monitored by the immune system.

HSP gp96 is one of the most abundantly expressed proteins in the human body and is expressed by all cells. It is normally retained within cells in a compartment called the endoplasmic reticulum (ER), where it facilitates the folding of newly synthesized proteins so that they may perform their various tasks properly. Gp96 is particularly important in the process of detecting antigens as it is present in all cell types, it is able to recognize all antigens. It also induces the immune system to activate CD8+ (“killer”) T cells which then seek out and destroy the cells that are marked by antigens. Gp96 is normally only contained inside the ER of cells, however when a cell dies an abnormal death through necrosis it breaks open and releases gp96 into the surrounding tissue microenvironment. *ImPACT* works by modifying the chemical structure of gp96 so that a cell can continuously release it into the extracellular space accompanied by the unique peptide that it is folding at the time without causing necrosis. This allows the immune system to seek out and destroy cells characterized with antigens before the body would otherwise have detected them.

### ***ImPACT Technology Overview***

A limitation of utilizing gp96 as a cancer immunotherapy is that it is normally retained within cells by a small region called a “KDEL sequence” that acts like a “leash”, preventing gp96 from leaving the ER. Therefore, in order to utilize gp96 as a therapeutic, gp96 must either be purified from individual cells or engineered to be secreted from cells.

To overcome this limitation, a team of scientists led by Eckhard Podack, MD, Ph.D., the Chairman of our Scientific Advisory Board and the inventor of our technology, deleted this KDEL sequence and replaced it with another sequence that causes the new fusion protein, called gp96-Ig, to be released from cells continuously. Multiple tumor cell lines were then made to express gp96-Ig, and as expected, secreted it continuously into the extracellular space in a complex with tumor proteins. Dr. Podack demonstrated in the laboratory that gp96-Ig vaccination effectively cross-presented tumor specific antigens to immune cells, led to expansion of Cytotoxic T Lymphocytes (CTL) and the subsequent rejection of injected tumor cells. Importantly, these studies demonstrated that the secreted protein gp96-Ig maintained the critical characteristics of the native gp96 protein required to generate anti-tumor immune responses. **Thus, *in vitro* proof-of-principle was established that the innovation, gp96-Ig, not only retained the desired properties of the native gp96 protein, but enhanced those functions and led to tumor-killing immune responses.**

***Our ImPACT technology platform:***

· ***Effectively cross-presents tumor antigens and leads to cytotoxic killer T cell activation***

Published studies in mice showed that killer T cell activation was approximately 10 million times greater with *ImPACT* secreted gp96-Ig than with a corresponding gp96 protein injection. The modified cell secretes gp96 in a sustained release for several days after injection. This creates a sustained immune response. Additionally, the immune response killed tumor cells, releasing additional gp96 and creating a continuous response loop that supports persistent activation of killer T cells. These data suggest that gp96-chaperoned peptides may represent the most efficient, robust pathway for presenting a cell's antigens to the immune system and activating killer T cell.

· ***Binds and presents all potential tumor antigens to the immune system simultaneously***

A single type of tumor (or virus) might have multiple strains derived from numerous tumor cells. These different strains have different antigens, all of which are capable of initiating an immune response. By creating a vaccine from a native tumor-cell line, we believe that *ImPACT's* technology can develop a therapy that shares many common features with patients' tumors of the same origin. We believe this "blanket" approach will provide each patient with a higher likelihood of a positive response to the therapy.

· ***Features killer T cell activation that is independent of CD4+ T cell help***

Animal studies have confirmed that our technology initiates a mechanism called cross-presentation that is critical to inducing tumor rejection. Importantly, it does this independently and successfully without additional CD4+ T cell recruitment, which is typically required in a normal immune system response. This is particularly important in cancer and HIV because helper T cell activity is frequently impaired in these disease states.

· ***May cause few side effects***

We believe our technology allows the body to recognize cancer as a foreign entity and uses the body's natural immune mechanism to recognize and fight it. In doing so, we believe our product candidates will generate fewer side effects than conventional chemotherapy and that patients will be able to maintain a higher quality of life.

The distinguishing characteristics of *ImPACT* are:

- (i) While most other immunotherapy approaches target only a single antigen, **Heat's patented approach uses modified heat shock proteins to stimulate an immune response against multiple antigens contained within cancer cells.** Cancer cells express different antigens that can be used to initiate an immune response. Each *ImPACT* vaccine is created from a native tumor-cell line that we believe expresses the widest array of antigens common to a particular type of cancer. We believe this "pan-antigen" approach provides each patient with a higher likelihood of a response to the therapy.
- (ii) Heat's product candidates are made from "off-the-shelf" (allogeneic) cells and may therefore be **less expensive to manufacture than patient-specific (autologous) vaccines.** Heat's vaccines are mass-produced from a single source while other immunotherapy approaches require physicians to extract a patient's blood and/or cells, send them to a facility where a personalized vaccine is created, and then have them shipped back to the physician for injection into the patient.

- (iii) While competing companies are developing therapies that are both “off-the-shelf” and which target multiple antigens, **Heat’s *ImPACT* technology is the only known “off-the-shelf” (allogeneic) vaccine to us that directly induces “cross-presentation” to the CD8+ (“killer”) T cells, which are the cytotoxic arm of the immune system.** Stimulating these CD8 (killer) T cells through “cross-presentation” has recently been shown to be critical to the induction of effective anti-tumor immunity. We believe our product candidates are able to leverage gp96 to serve as their own powerful immune stimulant (adjuvant) while other companies’ technologies rely on the use of a secondary adjuvant like GMCSF or Alum.

## **Our Product Candidates and Clinical Development Programs**

We have initiated development programs to target our *ImPACT* technology platform against a range of diseases, including non-small cell lung cancer, bladder cancer, breast cancer and ovarian cancer. We have submitted an IND and intend to submit a protocol for and initiate a Phase 2 clinical trial with our first therapeutic vaccine, HS-110, against NSCLC in 2H-2013, and we are planning to initiate a Phase 1/2 clinical trial for bladder cancer in Q3-2013. We plan to initiate Phase 1 trials for breast and ovarian cancer in 2014, pursuant to receiving additional non-dilutive grants and/or other financings. Our lead scientist has also completed a study in primates for the development of a therapeutic and prophylactic vaccine for the treatment and prevention of HIV. This study continues to be fully funded by the NIH. The HIV trials were initiated by the primary inventor and to date have been funded by grants awarded to the primary inventor, which can be used in the discretion of the inventor. We have no funding obligation for such trials and the primary inventor is responsible for future development and research; nonetheless any research conducted by the primary inventor contributes to our body of research and we may choose to progress any such research to further clinical trials and incorporate such research into our future development plans.

### **Summary of HS-110 Clinical Trial**

#### ***Phase 1 HS-110 Clinical Trial***

##### *Background*

A Phase 1 clinical trial with HS-110 in patients with very late stage IIIB/IV NSCLC was undertaken by the inventor of the technology which we license at the Sylvester Comprehensive Cancer Center with a total of 18 patients dosed, 15 of which completed the first course of three planned courses of therapy and were evaluated. Two of these 15 patients completed all three planned courses. The primary purpose of this trial was to evaluate safety of HS-110, while the secondary objectives were to study gp96-Ig specific immune responses and to monitor clinical progress. The patients were divided into 3 arms. Due to statistical and safety considerations and early termination of the study, the patients in the trial were not evenly divided among the three arms. Arm 1, which consisted of 11 patients, received 40 million cells every two weeks for 18 weeks, arm 2, which consisted of 4 patients, received 20 million cells every week for 18 weeks and arm 3, which consisted of 3 patients, received 10 million cells twice a week for 18 weeks. Three of the patients, who were late stage lung cancer patients, died before their immune response could be evaluated and were not included in the evaluation set at the end of the trial.

The Phase 1 trial was conducted under an investigator-sponsored IND and was fully funded by the NIH. The main criteria for inclusion were: (i) patients with histologically confirmed NSCLC stage IIIB, stage IV, or recurrent disease; (ii) at least one site of bi-dimensionally measurable disease; (iii) treated brain metastasis must be stable by CT scan or MRI for at least 8 weeks; (iv) patient must have received and failed at least two lines of therapy (one of them erlotinib); (v) age  $\geq$  18 years; ECOG performance status 0-2; life expectancy  $\geq$  3 months; and (vi) signed informed consent.

The median age was 67 years (range 38-86). HS-110 showed no overt toxicity. There were no serious adverse events (SAEs) that were considered by the trial investigator to be treatment-related. Most of the adverse events (AEs) were reported as mild or moderate (grade 1 or 2) with the most frequent being skin induration and rash that were transitory and usually resolved in 1 to 2 weeks.

HS-110 provides evidence of a CD8-CTL IFN- $\gamma$  immune response in patients with advanced NSCLC. In 11 of the 15 patients (73%) that completed the first course of therapy with HS-110, there was a twofold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN- $\gamma$ ). These patients also exhibited an estimated median survival of 16.5 months (95% CI:7.1-20.0). In contrast, 4 patients were immune non-responders and survived 2.1, 2.3, 6.7, and 6.7 months, or a median survival of 4.5 months, which is consistent with the expected survival times in this patient population. The protocol required that we look for such responses, but, as is typical in immunotherapy, no partial or complete tumor responses were observed. The median one-year overall survival rate of patients in the

study was 44% (95% CI:21.6-65.1). For comparative purposes, while there was a wide range of survival times, the one-year overall survival rate in a published one-year, 43-patient, advanced lung cancer population was 5.5%. One of the late-stage lung cancer patients is surviving over four years since starting the therapy and another patient is surviving over three years since starting the therapy. These findings were consistent with multiple pre-clinical published studies on *ImPACT* therapy.

#### HS-110 Safety

We believe HS-110 showed no overt toxicity. There were no serious adverse events (SAEs) that were considered by the trial investigator to be treatment-related. Most of the adverse events (AEs) were reported as mild or moderate (grade 1 or 2) with the most frequent being skin induration and rash that were transitory and usually resolved in 1 to 2 weeks. There were no immune-related events with the vaccine or the vaccinations.

Skin reactions at the vaccination site were minimal and of short duration and there was no evidence of the generation of any autoimmune phenomena. In lieu of a dose escalation design, the design of the Phase I trial involved increasing the frequency of vaccination, while still retaining the total dose of vaccine cells administered. A more frequent vaccination schedule caused increased tumor rejection in preclinical models.

#### Adverse Events by Body System

Body System	Number of Events (N=219)	Severity Grade (# of events)
Inspection Site Reactions	166 (75.8%)	Grade 1 (166)
Respiratory System	9 (4.1%)	Grade 2(5)
Body As a Whole (general disorders including fever)	8(3.7%)	Grade 1(4) Grade 2(3) <sup>a</sup> Grade 3(1) <sup>b</sup>
Nervous System	8(3.7%)	Grade 2(1)
Musculoskeletal	7(3.2%)	Grade 2(5)
Digestive System	7(3.2%)	Grade 1(7)
Metabolic and Nutrition	6(2.7%)	Grade 1(6)
Skin and Appendages (non-injection site reactions)	4(1.8%)	Grade 2(1)
Cardiovascular System	2(0.9%)	Grade 2(1)
Urogenital System	1(0.5%)	Grade 1(1)
Endocrine System	1(0.5%)	Grade 2(1)
Hemic and Lymphatic	—	—

a All grade 2 AEs except 4 were classified as non-related to treatment. The grade 2 treatment-related AEs were 1 musculoskeletal event (joint pain) rated as definitely related. 1 musculoskeletal event (knee weakness) rated as possibly related. 1 endocrine event (hot flashes) rated as unlikely related and 1 skin event (pruritus) rated as unlikely related.

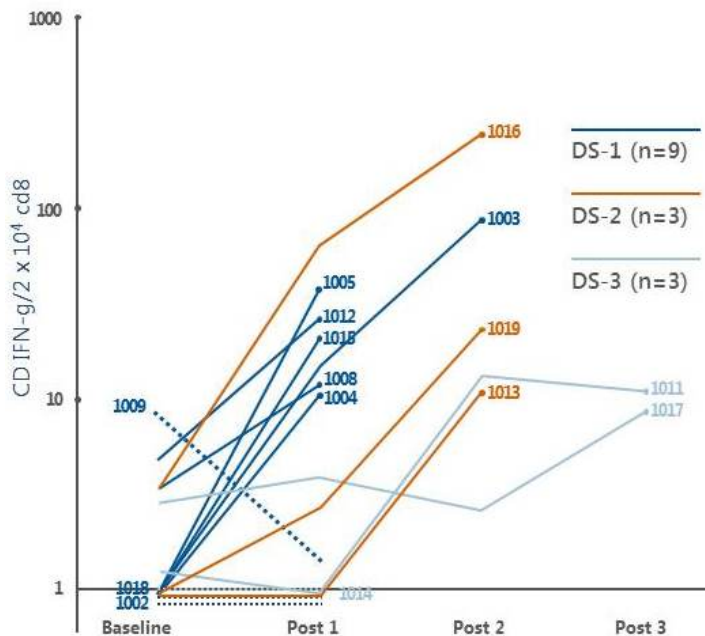
b The single grade 3 AE was in the body as a whole category (fatigue) and was rated as possibly related.

#### Injection Site Reactions

Injection Site Reaction (ISR)	Number of Events (N = 166)
Pain	17 (10%)
Induration	58 (35%)
Pruritus	8 (5%)
Hyperpigmentation/Discoloration	3 (2%)
Rash	78 (47%)
ISR non-specific	2 (1%)

*Positive Immunological Response*

In 11 of the 15 patients (73%) completing the first course of therapy with HS-110, there was a twofold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN- $\gamma$ ) following vaccination.



CD8 IFN- $\gamma$  response. Samples from 15 patients collected for immune response at baseline and after at least one course of vaccination were available for analysis of the CD8 IFN- $\gamma$  response. 20,000 purified patient CD8 T cells were stimulated with vaccine cells for 40h in ELI-spot plates and the frequency of IFN- $\gamma$  secreting cells determined. + indicates first increase. Solid indicate immune response (IR+), dashed lines no response (IR-).

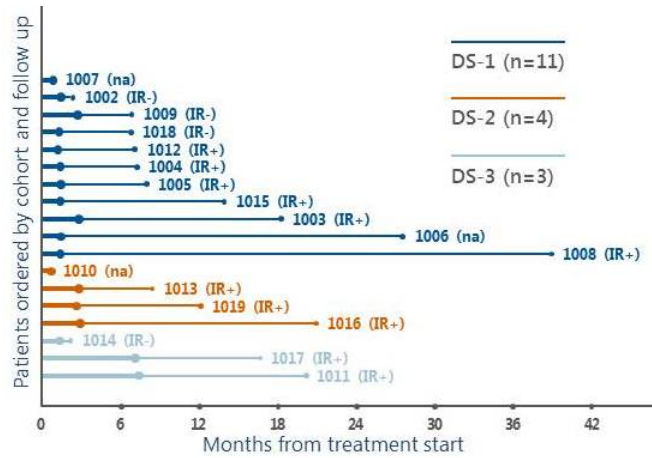
Since NSCLC is known to be highly immunosuppressive, we believe that by overcoming tumor-induced-suppression with frequent vaccinations as observed anecdotally in the Phase 1 study and the generation of an observed potent polypeptide specific CD8 CTL is encouraging and warrants further study.

*Clinical Response*

Seven of 15 patients completing the first course of therapy (39%; 95% CI: 17.3- 64.3%) achieved disease stabilization after the first course of vaccinations (6 weeks) and 8 patients had disease progression. While the protocol required that we look for such responses, as is typical in immunotherapy, no partial or complete tumor responses were noted in the study. Although clinicians and patients may perceive disease stabilization as beneficial, without a control arm FDA does not consider it to be a clinical benefit for regulatory purposes. In order to obtain FDA approval, we will be required to show an improvement in progression-free survival (or, PFS) or overall survival when compared to a control arm in a randomized study. The Kaplan Meier estimate of median time to progression was 1.4 months (95% CI: 1.3-2.7), and the PFS rates at 1, 2 and 3 months were 88.9% (95% CI: 62.4- 97.1%), 38.9% (95% CI: 17.5-60.0%), and 11.1% (95% CI: 1.9-29.8%), respectively. Of note, two patients remained progression free for just over 7 months.



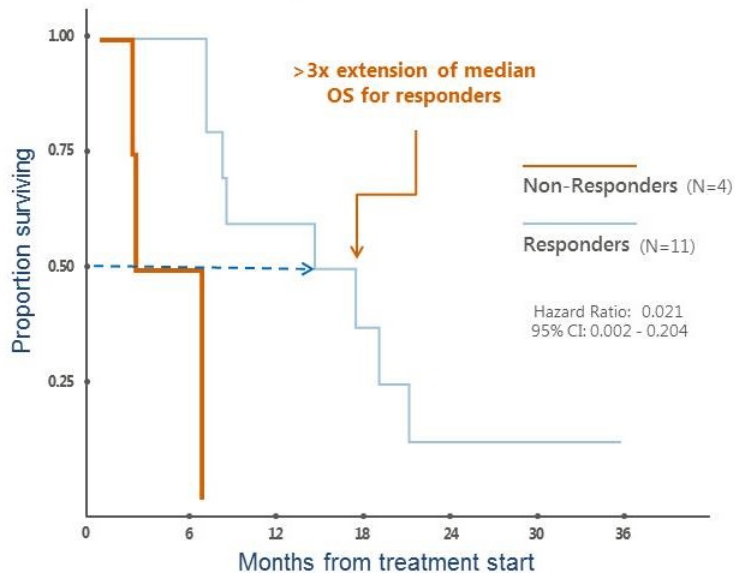
The typical median survival period for late-stage lung cancer is 4.5 months for patients who are not receiving any treatment. As of March 2013, 2 of the 15 patients who completed the first course of therapy remain alive and have been followed for over 3 years and 4 years, respectively. The Kaplan-Meier estimate of median survival was 8.1 months (95% CI: 6.7- 18.2), and the 1, 2, and 3-year OS rates were 44.4% (95% CI: 21.6-65.1%), 19.0% (95% CI: 4.8- 40.3%), and 9.5% (95% CI: 0.8-32.1%), respectively. While these results may be encouraging, apparent differences in outcome between population-based survival estimates and treatment groups from a clinical study can arise from differences other than drug treatment. The reliability of such comparisons must also be considered in light of the unblinded nature of the study data at the time that the comparator was chosen. Moreover, the wide range of values in the 95% confidence intervals in our study suggests that the actual median survival times could lie anywhere in the reported intervals.



Time to progression (thick line) and additional follow up (thin line) by dose-schedule cohort. Patients are shown within cohort in order of increasing follow up (shortest at top). Filled diamonds indicate disease progression; open diamonds indicate stable disease at last assessment. Filled circles indicate death; open circles last follow up of surviving patients. IR+: more than twofold increase in CD8 from baseline. IR-: no CD8 immune response. na: not assessed for immune response.

In 11 of the 15 patients (73%) completing the first course of therapy with HS-110, there was a twofold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN- $\gamma$ ) following vaccination. In a non-prespecified analysis, the responders saw a threefold increase in median overall survival compared to the non-responders on the trial.

## Immune Response Predictive of Survival



### Summary

In summary, based on the results of this Phase 1 trial in 18 patients, we believe HS-110 showed no overt toxicity and appears to be capable of generating CD8-CTL IFN- $\gamma$  immune responses in patients with advanced NSCLC. These results are encouraging and may be predictive of clinical benefit based on stabilization of disease, overall survival and the immune responder results.

### ONCOLOGY INDICATIONS of *ImPACT*

#### Lung Cancer

##### *Disease*

Lung cancer is the leading cause of cancer-related death in the United States. According to the National Cancer Institute, in 2013, lung cancer is expected to account for 26% of all female cancer deaths and 28% of all male cancer deaths. An expected 228,190 people will be diagnosed with lung cancer in the United States in 2012. Of these lung cancers, roughly 85% will present as non-small cell lung cancer. Patients with advanced clinical stage IIIB/IV disease visible on chest radiography have a 5-year survival rate as low as 1-5%.

##### *Clinical Development*

The technology that we license was the subject of an investigator initiated Phase 1 clinical trial conducted at the Sylvester Cancer Center for the treatment of non-small cell lung cancer ("NSCLC" or "lung cancer") to establish safety and proof of concept clinical efficacy.

After completion of the 18 patient Phase 1 trial, in which 15 patients completed the first course of three planned course of therapy and were evaluated, we successfully opened a new IND to conduct additional trials with HS-110 in patients with NSCLC. Our Phase 2 study, which has not yet been reviewed by FDA, has been designed as a maintenance therapy study in patients with Stage III/IV NSCLC who have completed a 1<sup>st</sup> line regimen consisting of a platinum doublet, crizotinib or erlotinib and achieved at least stable disease. The trial is structured as a multicenter

randomized, double-blind, placebo-controlled study to evaluate the immune response, safety and efficacy endpoints of HS-110 when administered weekly for 18 weeks in patients with non-small cell lung cancer (NSCLC). We anticipate opening approximately 15-20 clinical sites and enrolling approximately 125 patients with an expected enrollment period of 2.5 years. The trial is a 3-stage design. In stage 1 (dose-finding), patients will be randomized to either placebo treatment, low dose HS-110 ( $2 \times 10^6$  cells) or high dose HS-110 ( $1 \times 10^7$  cells), administered weekly for 18 doses (18 weeks). In stage 2 (proof of concept), patients will be randomized to either placebo treatment or HS-110 at the dose determined to produce the optimal immune response in Stage 1. In Stage 3 (biocomparability), patients will be randomized to one of two preparations of HS-110 administered weekly for 18 weeks at the dose determined to produce the optimal immune response in Stage 1. The primary endpoint in Stages 1 and 3 will be immune response; the primary endpoint in Stage 2 will be progression-free survival. All stages will examine additional secondary endpoints including overall survival.

In addition to our Phase 2 study, our chief scientist has received a grant award from the Marcus Foundation that fully funds a 36 patient Phase 1/2 investigator-sponsored Phase 1/2 study for use of HS-110 as a combination therapy with theophylline and oxygen. We expect that he will begin this study in Q3-2013.

## **Bladder Cancer**

### ***Disease***

In the United States, bladder cancer is the fourth most common type of cancer in men and the ninth most common cancer in women. According to the National Institutes of Cancer, 1 in 42 men and women will be diagnosed with bladder cancer during their lifetime, a total of more than half a million patients in the US. There are more than 60,000 cases of bladder cancer diagnosed each year in the United States, resulting in over 14,000 deaths per year. Available treatments are currently not effective, thus this remains an area of high unmet need.

### ***Clinical Development***

#### ***The Bladder Cancer Phase 1/2 Trial***

cGMP-grade cell lines are currently being developed that will be used to treat patients with advanced bladder cancer. It is anticipated that these cellular vaccines will be completed by the 3rd quarter of 2013, with a Phase 1/2 clinical trial beginning that same quarter. In parallel with our clinical development plans, we have engaged a vendor as our clinical grade contract manufacturer for our future potential Phase 3 trial.

Preparation of IND documents in support of HS-410 for bladder cancer are in progress. We anticipate IND activation in 2013. This IND will include a 93 patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 6 weekly intravesical bacillus Calmet-Guerin (BCG) immunotherapy installations. We anticipate including approximately 8-10 clinical sites with an enrollment period of 12-18 months.

The Phase 1 portion will randomize 18 patients in 1:1 fashion to either a high or low dose group. Patients will receive weekly intradermal injections of HS-410 for 18 weeks and immune response will be evaluated at baseline, week 6, week 12 and week 18. The first 4 patients in each dose group will be enrolled at 2 week intervals to allow opportunity to assess safety and tolerability of HS-410. At the completion of the Phase 1 portion of the study, the dose resulting in the optimal immune response will be advanced to Phase 2. In the Phase 2 portion, 75 patients will be enrolled in 2:1 fashion to HS-410 or placebo. Primary endpoint will examine time to 1<sup>st</sup> recurrence of bladder cancer. Other endpoints will include recurrence rate, progression rate and immune response. Depending on the results of this Phase 1/2 study and the prevalence of the disease, we may seek designation of HS-410 as an orphan drug.

## **Triple Negative Breast Cancer**

According to the American Cancer Society, there will be 234,580 new cases of breast cancer diagnosed in 2013. Approximately 10-20% of those cases will be triple negative breast cancer (TNBC), an aggressive form of the disease marked by earlier age of onset, worse clinical outcome, and a higher rate of local relapse. This disease cannot be treated by hormone therapy or receptor-directed monoclonal antibodies. New approaches for treatment to prevent relapse in this disease after early treatment need to be investigated.

## **Clinical Development**

### *The TNBC Phase 1 Trial*

We are currently developing cGMP grade cell lines that will be studied in the treatment of patients with TNBC. It is anticipated that these cell lines will be ready for use by the 3rd quarter of 2013.

## **Ovarian Cancer**

### *Disease*

Ovarian cancer accounts for about 3% of all cancers among women and ranks the second among gynecologic cancers. According to the American Cancer Institute, an estimated 22,240 new cases are expected in the US in 2013. Ovarian cancer causes more deaths than any other cancer of the female reproductive system, and will lead to an estimated 14,030 deaths in the United States in 2013. Due to the prevalence of ovarian cancer and its poor prognosis, particularly when discovered late, the development of novel therapeutics for the treatment of ovarian cancer is a high priority.

### *Clinical Development*

We are currently developing cGMP-grade cellular vaccines that will be studied in the treatment of patients with advanced serious ovarian carcinoma. These cell lines were ready for use in early 2013, with a Phase 1 clinical trial beginning in mid-2014.

### **Other Cancers**

Our *ImPACT*-technology is a broad based approach and can be used to combat a variety of cancers. We are in the process of identifying available cell lines, such as pancreatic cancer, melanoma, glioblastoma, and vesicular lymphoma. We expect to have several additional *ImPACT*-based products in the clinic in 2014.

### **Infectious Diseases**

To date, over \$4,000,000 in governmental and institutional funding has been provided to the inventor of the technology we license for HIV and hepatitis C virus (HCV) research using our *ImPACT*-technology. We do not intend to use any of the proceeds of this offering to further any HIV or HCV research and instead plan to conduct additional research with respect to the use of our *ImPACT*-technology for the treatment of such diseases solely through additional governmental and institutional grants, if any, that may be received.

### **Manufacturing**

We rely on third-party manufacturers to produce and store our product candidates for clinical use and currently do not own or operate manufacturing facilities. The HS-110 used in the inventor's Phase 1, and planned for use in our Phase 2 clinical trial, was and is currently manufactured by our contractors under current good manufacturing practices, or cGMP.

We have retained a vendor, who has begun production of HS-110 to be used in Phase 2 and our potential Phase 3 clinical trials. We entered into an eight year Manufacturing Services Agreement, dated October 19, 2011, with the vendor (the "Manufacturing Agreement"). The Manufacturing Agreement provides that the vendor will manufacture products based on our *ImPACT* technology intended for use in pharmaceutical or medicinal end products, including, without limitation, products in a final packaged form and labeled for use in clinical trials or for commercial sale to end users in accordance with the terms and conditions of individual statements of work. The Manufacturing Agreement requires that we purchase certain minimum amounts each year from the vendor. The Manufacturing Agreement may be terminated by the parties upon mutual agreement, and by each party for a material breach by the other party that is not cured within the cure period, upon notice that a clinical trial for which product is being produced under the agreement is suspended or terminated or upon the other party's insolvency, dissolution or liquidation.

The HS-110 used in our clinical trials was and is currently manufactured under cGMP. The vaccine is grown in large quantities and quality tested according to FDA guidelines. Following testing, the vaccine is irradiated, which is a commonly used attenuation process that eliminates the ability of the gp96-Ig-containing vaccine cell lines to replicate but allows them to continue secreting gp96-Ig for a period of several days. Quality tested, irradiated batches of the vaccine are then dispensed into individual doses and frozen in liquid nitrogen. These batches of frozen vaccine are stable for long periods of time, and are thawed immediately prior to administration to patients. Sufficient material to complete the HS-110 Phase 2 study has already been produced, and preparations are underway to produce quantities required for subsequent clinical trials.

## Competition

The pharmaceutical industry and biologics industry are each highly competitive and characterized by a number of established, large pharmaceutical companies and other companies, as well as smaller companies like ours. If our competitors market products that are less expensive, safer or more effective than any future products developed from our product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to our research and development activities.

As a biotech company with a cancer immunotherapy as its lead therapeutic, we compete with a broad range of companies. At the highest level, cancer immunotherapy can be seen as both a complement and a potential competitor to any oncology therapy, most notably chemotherapy, biologics and small molecule drugs. Not only do we compete with companies engaged in various cancer treatments including radiology and chemotherapy but we also compete with various companies that have developed or are trying to develop immunology vaccines for the treatment of cancer. Certain of our competitors have substantially greater capital resources, large customer bases, broader product lines, sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than we do and have more established reputations as well as global distribution channels. Our most significant competitors, among others, are fully integrated pharmaceutical companies such as Eli Lilly (Alimta), Bristol-Myers Squibb (Erbix) and Sanofi-Aventis (Eloxatin), and more established biotechnology companies such as Roche/Genentech (Avastin and Tarceva), and competing cancer autologous immunotherapy companies such as Dendreon and others which have substantially greater financial, technical, sales, marketing, and human resources than we do. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are less expensive, safer or more effective than those being developed by us or that would render our technology obsolete. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches.

We expect to compete with other pharmaceutical and biotechnology companies, and our competitors may:

- develop and market products that are less expensive, more effective or safer than our future products;
- commercialize competing products before we can launch any products developed from our product candidates;
- operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- a more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We expect to compete for market share against large pharmaceutical and biotechnology companies, smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations.

Many major pharmaceutical companies have at least one immunotherapy drug or therapeutic in development, either directly or in partnership with a smaller biotech firm. Some of our competitors that are developing competitive immunology drugs and therapeutics include Merck kGaA/Oncocyte's Stimuvax for the treatment of breast cancer and NSCLC; Transgene and its product TG4010 for the treatment of NSCLC lung cancer; GlaxoSmithKline and its product MAGE-A3 for the treatment of melanoma, NSCLC, multiple myeloma and squamous cell carcinoma; Oxford BioMedica and its product TroVax for the treatment of prostate, kidney and colorectal cancer; NewLink Genetics and its treatment for pancreatic cancer and lung cancer; Celldex/Pfizer and their product CDX-110 for the treatment of malignant brain cancer; and Dendreon and its product Provenge for the treatment of prostate cancer.

The primary treatments for non-small cell lung cancer are surgery, radiation, chemotherapy and various combinations of each of these treatments. A large number of patients, particularly with advanced disease, are refractory to these treatments and are subsequently treated with a number of emerging biologic agents, including immunotherapy. Some examples of therapies commonly attempted with stage IIIB/IV NSCLC patients include: Alimta (pemetrexed), Avastin (bevacizumab), Tarceva (EGF inhibitor), Gemzar (gemcitabine), Erbitux (cetuximab), Carboplatin, Taxol, VP16 and Arlibercept. It is unlikely that biologic agents will compete with more traditional therapies in the short-term, but many oncologists believe that such therapies will eventually become the mainstay of lung cancer therapy. None of these agents have proven particularly effective for stage IIIB/IV NSCLC patients, with the most effective therapies only increasing survival by a few months. As a result, we do not consider these agents to be direct competitors to HS-110 because they are likely to be given either in sequence or in conjunction with some of the agents listed. Furthermore, many patients cannot tolerate many of the chemotherapeutics listed. Thus, we believe if HS-110 has a positive safety profile (without observation of local or systemic toxicities, none of which have been seen to date), it is likely that HS-110 would be preferred both by physicians and patients in this stage of disease.

As previously stated we compete with other forms of cancer treatment such as biologic therapies in addition to immunology therapies. There are several biologic therapies in clinical development against NSCLC that have been identified as potential competitors to HS-110. In particular, a cell-based vaccine therapy, Lucanix, is in development by NovaRx. Lucanix has entered Phase 3 clinical trials.

Our strategy is to emphasize what we believe to be our competitive advantages which are that the therapy will have less side effects than most other chemotherapies, will be available at lower prices than other therapies and will work on almost all types of cancer and not just one specific type.

Although all chemotherapy drugs have severe side-effects such as overall damage to the immune system, not only to cancerous cells, leading to hair loss, nausea and vomiting, and considerable pain, etc., the side effects from immunotherapy are typically reduced because immunotherapy works with the body's own immune response.

According to Schreiber et al, patient-specific vaccines are not more effective than off-the shelf vaccines in reducing tumors. Furthermore, patient-specific vaccines cost far more to produce than off the shelf (allogeneic) vaccines, where any donor tissue can be used. Over 95% of newly developed cancer immunotherapies cost over \$20,000 per course of treatment.

#### ***Grant Funding***

To date, in excess of \$14,000,000 in grants, have been awarded to the primary inventor of the technology we license to fund development of *ImmPACT* technology and clinical trials upon which our clinical programs are based. 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 inventors 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. Our strategy is to continue to apply for grants that will enable us to leverage our core technology platform. We have applied for grant funding in the amount of approximately \$17,000,000 from

the NIH, DOD, CPRIT and other public and private foundations to be used to expand our lung cancer clinical trial and commence other research and development activities, however, there can no assurance that such grant funding will be awarded to us. Our primary inventor also applies for academic grants to enhance the core technology platform. Grant funds received by our primary inventor are not utilized by us. Rather, these funds support our primary inventor's academic interests and may benefit us to the extent that these grants enable him to enhance the technology platform or generate additional data to support our programs. Currently, our primary inventor's academic grants are supporting the HS-110 NSCLC combination study as well as the HIV study. All other clinical programs, including our Phase 2 NSCLC study and our Phase 1/2 bladder cancer study are supported by us.

**Previous Grant awards for development of *ImPACT***

Grant Title	Granting Organization	Amount
Regulation of Anti-Tumor Immunity	NIH	\$6,187,904
Molecular Mechanism of Anti-Tumor and Anti-Bacterial Cytotoxicity	NIH	\$897,295
Mechanisms of mucosal protection by HPV-SIV and gp96-Ig-SIV vaccines	NIH	\$2,000,000
Systemic and mucosal HIV-immunity by HSP-gp96 vaccines	NIH	\$451,410
Induction of mucosal SIV immunity in non-human primates by secreted HSP-gp96	NIH	\$2,124,733
Clinical Translation of Gene Therapy for Lung Cancer Award Recipient	Alliance for Cancer Gene Therapy	\$1,000,000
Clinical Translation of Gene Therapy for Lung Cancer Award Recipient	State of Florida	\$100,000
QTDP Grant	Dept. of Treasury	\$244,479
Use of HS-110 as a Combination Therapy with Theophylline and Oxygen in Advanced Lung Cancer Patients	Marcus Foundation	\$840,000

**Intellectual Property**

**License Agreements and Intellectual Property**

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets and rights in our unique biological materials, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the strongest intellectual property protection possible for our current product candidates (*ImPACT* therapy) and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. See “Risk Factors - Risks Relating to Our Business” – “We have limited protection of our intellectual property.”

We will continue to depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

## License Agreements

In July 2008, we entered into an exclusive license agreement with the University of Miami (the “University”) for intellectual and tangible property rights relating to *ImPACT*, technology. This license agreement was subsequently assigned to our subsidiary Heat Biologics I, Inc. which issued to the University shares of its common stock representing seven and one half percent (7.5%) of its common stock, of which 5% was non-dilutable until our receipt of the proceeds of our recent Series B-1 Preferred Stock private placement in March 2013. The term of the license is the length of the last to expire patent, unless terminated earlier. The license agreement grants Heat Biologics I, Inc. exclusive, worldwide rights to make, use or sell licensed materials based upon the following patent-related rights:

- U.S. patent applications: Serial number 60/075,358 (the “ ‘358 application”) entitled “Modified Heat Shock Protein-Antigenic Peptide Complex” and filed on February 20, 1998; Serial number 09/253,439 (the “ ‘439 application”) entitled “Modified Heat Shock Protein-Antigenic Peptide Complex ” and filed on February 19, 1999; serial number 11/878,460 (the “ ‘460 application”) entitled “Recombinant Cancer Cell Secreting Modified Heat Shock Protein-Antigenic Peptide Complex” and filed on July 24, 2007; and all U.S. patents and foreign patents and patent applications based on these U.S. applications; as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the ‘358, ‘439, or ‘460 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “GP96 Vaccine Technology Portfolio”).

As consideration for the rights granted in the license agreement, the licensee is obligated to pay the University upfront license fees, additional yearly and milestone payments and a royalty based on net sales of products covered by the patent-related rights set forth above. More specifically, the licensee is obligated to pay the University (i) all past and future patent costs associated with the licensed patent-related rights; (ii) a license issue fee of \$150,000; (iii) annual payments of \$10,000 in 2010, 2011 and 2012, and \$20,000 each year thereafter; (iv) a milestone payment of \$250,000 by the earlier of May 31, 2017 or approval of a BLA for the lung cancer vaccine or for a cancer vaccine other than lung cancer; and (v) royalties equal to a percent (ranging from low to mid single digits ) of net sales of licensed products. The royalty rate is subject to reduction if additional license rights from third parties are required to commercialize licensed products. In the event of a sublicense to a third party, Heat Biologics I, Inc. is obligated to pay royalties to the University equal to a percentage of what it would have been required to pay to the University had it sold the products under sublicense itself. In exchange for additional consideration, the University has agreed to postpone the payment due dates of this license agreement. To date, a total of \$360,113 has been paid to the University with respect to such license agreement. The license agreements provide that the licensor has the right to terminate the license if we have not introduced, or at least used our best efforts to introduce, a licensed product in the commercial marketplace in the US, EU, or Japan by December 31, 2020; and otherwise exercise diligence to bring licensed products to market or in the event of our insolvency or bankruptcy. In addition, either party has a right to terminate the license agreement upon a material breach of an obligation under the license agreement by the other party if such breach is not cured and we have the right to terminate upon 90 days notice. In the event of a termination, we are obligated to pay all amounts that accrued prior to such termination. In the event that we breach a material term of one or both of the license agreements, the University has the option to terminate the agreement following the giving of notice and an opportunity to cure any such breach. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia.

In February 2011, our subsidiary, Heat Biologics I, Inc., entered into four additional exclusive license agreements with the University. The terms of each of these additional licenses runs until all the patent-related rights licensed therein have expired, unless terminated earlier. In each of these additional exclusive license agreements, Heat Biologics I, Inc. obtained exclusive, worldwide rights to make, use or sell products covered under the following patent-related rights:

- U.S. patent application serial number 61/347,336 entitled “Cancer Treatment” and filed on May 21, 2010, all U.S. patents and foreign patents and patent applications based on these U.S. applications; as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “Cancer Treatment Portfolio”).



- U.S. patent application serial number 61/033,425 entitled “Allogeneic Cancer –Based Immunotherapy” and filed on March 3, 2008 and PCT application number PCT/2009/001330 “Allogeneic Cancer –Based Immunotherapy” filed on March 3, 2009, all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “Allogeneic Cancer –Based Immunotherapy Portfolio”).
- U.S. patent application serial number 61/033,425 entitled “Heat Shock Protein GP96 Vaccination and Methods of Using Same” filed on March 20, 2008 and PCT application number PCT/ 2009/001727 “Heat Shock Protein GP96 Vaccination and Methods of Using Same” filed on March 19, 2009, all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “Heat Shock Protein GP96 Vaccination Portfolio”).
- U.S. patent application serial number 61/116,971 entitled “HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity” filed November 28, 2008 and PCT application number PCT/ 2009/065500” “HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity” filed on November 23, 2009 all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “HIV/SIV Vaccine Portfolio”).

As consideration for the rights granted in these additional four license agreements, the licensee is obligated to pay the University certain upfront license fees, past and future patent costs and royalties based on net sales on commercialized products covered by the patent-related rights set forth above. No annual or milestone payments are required under any of these four additional license agreements. The upfront license fees for the Cancer Treatment Portfolio and the HIV/SIV Vaccine Portfolio license agreements are \$10,000 and \$50,000, respectively. No upfront license fees were required under the license agreements for the Allogeneic Cancer–Based Immunotherapy and the Heat Shock Protein GP96 portfolios. Under each of these four additional license agreements, the royalties are equal to a percent (ranging from low to mid single digits) of net sales of products covered by the patent-related rights in the respective license agreements. These royalty rates are subject to reduction if additional license rights from third parties are required to commercialize licensed products. In the event of a sublicense to a third party, Heat Biologics I, Inc. is obligated to pay royalties to the University equal to a percentage of what it would have been required to pay to the University had it sold the products under sublicense itself. Each of these additional license agreements also provide that the licensee will not have to pay more than above royalty rates and sublicense fees if more than one license from the University is required to sell products covered by the licensed patent-related rights. In exchange for additional consideration (including the requirement that Heat Biologics I, Inc. pay additional milestone payments of \$25,000 before initiation of any Phase 3 clinical trials for products covered by any of the license agreements, and an additional payment equal to 18% annual interest on the amounts due or a note convertible into an equivalent value of shares in Heat’s Preferred Stock), the University agreed to postpone the payment due dates for each of these four additional licenses. On April 26, 2013, the outstanding balances to the University under the license agreements were paid in full.

All five of the above-described license agreements provide that the licensor has the right to terminate a subject license if the licensee has (i) not introduced, or at least use it best efforts to introduce, a licensed product in the commercial marketplace in the US, EU, or Japan by December 31, 2020; (ii) not otherwise exercise diligence to bring licensed products to market; or (iii) files, or has filed against it, a proceeding under the Bankruptcy Act, is adjudged insolvent, makes an assignment for the benefit of its creditors, or has an unreleased or unsatisfied writ of attachment or execution levied upon it. In addition, upon an uncured material breach of an obligation under any one of these license agreements by a party, the other party has the right to terminate that agreement upon 90 days notice or 30 days notice if the breach relates to payments due to the University. In the event of a termination, Heat Biologics I, Inc. will be obligated to pay all amounts that accrued prior to such termination. Each of the license agreements also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee’s agreement to indemnify the University for liabilities arising out of the negligence of licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

In April 2013, we entered into an agreement with the University under which the University granted us an option to obtain an exclusive license to the following patent-related rights:

- U.S. patent application serial number 12/303,036 entitled "Perforin-2 Proteins" filed December 2, 2008 and U.S. patent application serial number 61/637,455 entitled "Perforin-2 Defense Against Invasive and Multi-drug Resistant Bacteria" filed Modified Heat Shock Protein-Antigenic Peptide Complex" and filed on April 21, 2012; all U.S. patents and foreign patents and patent applications based on these U.S. applications; as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the aforementioned applications) of the foregoing, and any re-examinations or reissues of the foregoing.

In consideration for the option, we are obligated to pay the University an option fee of \$2,000 and to reimburse the University \$3,000 for past patent costs. The term of the option is twelve months and is extendible so long as we continue to pay ongoing patent expenses.

In addition to the licenses obtained from the University, we have entered into agreements with (i) the Regents of the University of Michigan ("U.Mich"); and (ii) the American Type Culture Collection ("ATCC") for the evaluation of, acquisition of commercial rights to, certain biological materials.

In July 2011, we exercised an option agreement with U.Mich and entered into an exclusive license agreement with U.Mich to use, market, offer for sale, sell and/or sublicense materials and processes related to certain bladder cancer cell lines. The term of the license is perpetual, unless terminated earlier by us or by U.Mich. As consideration for the rights granted in the license agreement, we agreed to pay U.Mich up-front license fees and additional yearly and milestone payments. We also assumed under the license agreement responsibility for any infringement of third party rights caused by our use of the licensed materials. We paid an option fee of \$2,000, a license issue fee of \$10,000 and are obligated to pay an annual maintenance fee of \$10,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to \$50,000. In addition, we are obligated to make milestone payments of \$25,000, \$50,000 and \$75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial and \$250,000 upon the first commercial sale of a licensed product and \$350,000 upon annual net sales of \$100,000,000 or more. To date, we have paid \$22,000 to U.Mich. with respect to such license. The license agreements provide that the licensor has the right to terminate the license should we cease to carry on our business, fail to make a required payment or otherwise materially breach or default in our obligations under the license agreement following the giving of notice and an opportunity to cure any such breach. The license agreement provides that if we do not achieve the following milestones within the required period, U.Mich has the right to terminate the license agreement: completion of a Phase 1 clinical trial on or before January 1, 2015, a Phase 2 clinical trial on or before January 1, 2017, a Phase 3 clinical trial on or before January 1, 2019 and the first commercial sale of a product that includes the materials supplied by U.Mich on or before January 1, 2020. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia.

In April 2011 we entered into an evaluation and biological material license agreement with the ATCC to evaluate, use, market, offer for sale, sell and/or sublicense materials and processes related to various different cell lines. The agreement with ATCC provides for an evaluation term of twelve months subject to two additional renewals, and a non-exclusive commercial use license upon termination of the evaluation period to utilize the products we obtain in the evaluation to develop, make, use and sell licensed products. The agreement with ATCC has a term of forty years. We paid an evaluation fee and two renewal evaluation fees totaling \$15,000, and are obligated to pay a \$50,000 fee upon initiation of the commercial license and a less than 1% royalty based on sales of licensed products. In addition, we are obligated to make milestone payments of \$15,000, \$30,000 and \$60,000 upon initiation of a Phase 1, Phase 2, and Phase 3 trial, respectively; and \$200,000 upon receipt of marketing authorization. To date, we have paid \$15,000 to the ATCC with respect to such license.

Under the license agreements with the University, we have obtained exclusive rights to five different patent families directed to therapeutic compositions and methods related to our vaccine platform and preclinical development program for cancer. These families comprise five PCT applications, six granted patents, sixteen patent validations in European countries, two allowed patent applications and thirty-seven other pending patent applications. These patents and applications cover the United States, Europe and Japan as well as several other countries having commercially significant markets. For each platform or program, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including one or more of the following: our

available resources, the size of the commercial market, the presence of a potential competitor or a contract manufacturer in the market and whether the legal authorities in the market effectively enforce patent rights. The patent families associated with our *ImPACT* platform are:

**“Recombinant cancer cell secreting modified heat shock protein-antigenic peptide complex.”**

This family of patent filings relates to methods and compositions for enhancing an immune response. More particularly, the application describes the creation of a tumor cell therapy including a cancer cell that has been engineered to secrete a heat shock protein (gp96), and the use of such therapy to enhance an anti-tumor immune response. Within this family are one pending US application, one granted Australian patent, one pending Canadian application, one pending European application, two granted European patents (collectively validated in 16 countries), one pending Japanese application, and one granted Japanese patent. Not including any patent term adjustments or extensions (e.g., for patent office delays or extensions/exclusivity periods provided for new drug approvals in the US and some foreign countries), the term for patents in this family extends until 2019.

**“Heat Shock Protein gp96 Vaccination and Methods of Using Same”**

This family of patent filings also relates to methods and compositions for enhancing an immune response. It further describes: (a) how intraperitoneal gp96-Ig administration increases recruitment of innate immune cells into the administration site, mediates proliferation of dendritic cells (DCs) and CD8 cells, and activates natural killer (NK) cells; (b) that gp96-Ig-secreting cell vaccines are more effective when gp96-Ig is continuously released; (c) that frequent gp96 immunizations can overcome tumor-induced immune suppression and retards tumor growth; and (d) that B cell depletion can enhance gp96-Ig-mediated recruitment of NK cells and retention of DCs in the administration site. Within this family are one granted Australian patent, and one pending application each in the U.S., Canada, China, Europe, Israel, India, Japan, South Korea, and Hong Kong. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

**“Allogenic Cancer Cell Based Immunotherapy”**

This family of patent filings also relates to methods and compositions for enhancing an immune response. It further describes: (a) making vaccines cells allogeneic by expressing exogenous major histocompatibility complex (MHC) antigens; (b) B cell depletion to augment the effectiveness of the vaccines; and (c) the enhancement of anti-tumor immune responses using multiple immunizations less than two weeks apart. Within this family are one granted Australian patent, one allowed U.S. application, and one pending application each in Canada, China, Europe, Israel, India, Japan, and South Korea. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

**“Cancer Treatment”**

This family of patent filings contains results from a Phase 1 clinical trial of human subjects with cancer. Within this family are one pending application each in the U.S., Australia, China, Europe, India, Israel, Japan, and South Korea. Filings in Canada and Hong Kong are intended to be made before the respective deadlines. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2031.

**“HIV/SIV Vaccines to Generate Mucosal and Systemic Immunity”** Within this family are one allowed South African application, and one pending application each in the U.S., Australia, Canada, China, Europe, India, the Philippines, Singapore, and Hong Kong. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

This patent family relates to the use of host cells that have been engineered to secrete a heat shock protein (gp96) to treat various chronic viral infections including those caused by HIV.

## Government Regulation

### *FDA Approval Process*

In the United States, pharmaceutical products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of new drug applications, or NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug or biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are

undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding \$1,958,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$98,000 per product and \$526,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug or biologic products, or drug or biologic products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug or biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

#### ***Post-Approval Requirements***

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug and biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

#### ***Orphan Drugs***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

#### ***Fast Track Designation and Accelerated Approval***

The FDA is required to facilitate the development, and expedite the review, of drugs or biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request that the FDA designate the candidate for a specific indication as a fast track drug or biologic concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the drug or biologic candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request.

Under the fast track program and FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug or biologic candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

In addition to other benefits such as the ability to use surrogate endpoints and engage in more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the NDA or BLA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

#### ***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

#### ***Additional Controls for Biologics***

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

#### ***Biosimilars***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously

administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being evaluated by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

#### ***Cell and Tissue Based Biologics***

Establishments that manufacture cell and tissue based products must comply with the FDA's current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also include requirements for a unified registration and listing system, donor screening and testing, adverse reaction reporting, and labeling.

Cell and tissue based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use.

#### ***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

#### ***Non-U.S. Regulation***

Before our products can be marketed outside of the U.S., they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.



While we intend to market our products outside the United States in compliance with our respective license agreements, we have not made any applications with non-U.S. authorities and have no timeline for such applications or marketing.

### **Research and Development**

We have built an internal and external research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical and medicinal chemistry, manufacturing, clinical development and regulatory and quality assurance. We engage third parties on a limited basis to conduct portions of our preclinical research; however, we are not substantially dependent upon any third parties for our preclinical research nor do any of these third parties conduct a major portion of our preclinical research. Research and development expenses were \$902,938 and \$1,246,587 during the years ended December 31, 2012 and 2011, respectively.

### **Employees**

As of May 21, 2013, we had a total of 12 employees and consultants, of which 5 are full-time employees and 7 are part-time employees or consultants. We believe our relationships with our employees are satisfactory. None of our employees is represented by a labor union. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel to pursue our development program. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.

### **Facilities**

We lease approximately 2,111 square feet of office space in Chapel Hill, North Carolina under a lease that expired December 31, 2012, which could be extended for an additional 24 months on substantially the same terms. The monthly lease payments for these facilities, including common area maintenance and related operating expenses, were approximately \$3,870. On December 19, 2012, we entered into a lease modification agreement that extended the lease term until July 31, 2013 and the monthly rent was increased to \$4,046. Based on our current operational plans, we believe that such facilities are adequate for our operations for the near future.

### **Legal Proceedings**

There are currently no pending legal proceedings against the Company or its subsidiaries.

## MANAGEMENT AND BOARD OF DIRECTORS

### Board of Directors

Our business and affairs are organized under the direction of our board of directors, or our Board, which currently consists of five members. The primary responsibilities of our board are to provide oversight, strategic guidance, counseling and direction to our management. Our Board meets on a regular basis and additionally as necessary.

### Executive Officers and Board of Directors

Name	Age	Position	Served as an Officer or Director Since
Jeffrey Wolf	50	Chairman, Chief Executive Officer and Director	2008
Sandra Silberman, MD, Ph.D.	57	Chief Medical Officer	2013
Matthew E. Czajkowski	64	Chief Financial Officer	2013
Jennifer Harris, Pharm.D.	47	Vice President of Clinical and Regulatory Affairs	2011
Vadim Deyev, MD, Ph.D.	49	Director of Applied Research	2011
John Monahan, Ph.D.	67	Director	2009
Paul Belsky, MD	56	Director	2009
Michael Kharitonov, Ph.D.	49	Director	2009
Edward B. Smith	38	Director	2009

All of the officers listed above are full-time employees of the Company other than Mr. Czajkowski, Dr. Silberman and Dr. Harris who work on a part-time basis.

#### **Jeffrey Wolf, Chairman, Chief Executive Officer and Director**

Mr. Wolf founded Heat Biologics in August, 2008. Prior to founding Heat, from June 1997 to March 2011, Mr. Wolf has served as managing director at Seed-One Ventures, LLC a medically-focused venture capital firm. Since founding Seed-One, Mr. Wolf has founded and run several medical companies. Mr. Wolf's start-ups include Avigen, a San Francisco-based gene therapy company where he was a co-founder and director; TyRx Pharma, a Princeton-based company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; EluSys Therapeutics, a New Jersey company focused on the development of a novel technology to remove blood-borne pathogens where he was a co-founder, Chairman and Chief Executive Officer; and GenerationOne, a Miami-based company focused on mobile-based collaborative care, where he was the founder, Chairman and Chief Executive Officer. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics. Mr. Wolf serves as a director of several Seed-One portfolio companies and serves as a director of Synthetic Biologics, Inc., a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses.

We selected Mr. Wolf to serve on our Board as our chairman because he brings to the board extensive knowledge of the pharmaceutical and biotechnology industries. Having served in senior corporate positions in several biomedical companies, he has a vast knowledge of the industry and brings to the board significant executive leadership and operational experience. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies and his service on other public company boards provides him with extensive corporate governance knowledge.

#### **Sandra Silberman, MD, Ph.D., Chief Medical Officer**

Dr. Silberman began her career in clinical development at Pfizer, Inc., where from 1992-1999 she initiated the company's first program in clinical oncology and oversaw the introduction of Tarceva™ into clinical trials. From 2000-2004, she served as Senior Director for Novartis Clinical Research, where she led the global development of Gleevec(TM), a highly innovative drug and the first targeted therapy for chronic myelogenous leukemia. Dr. Silberman then joined Eisai Medical Research as Global Therapeutic Area Head (Oncology) in 2004 until 2006, a role in which she advanced six novel compounds into Phases I through III of clinical development. From 2009 until 2013, Dr. Silberman has served as Vice-President of Quintiles.

Dr. Silberman received her Ph.D. in Tumor Immunology from Johns Hopkins University and her M.D. from Cornell University Medical College. She completed a fellowship in hematology/oncology at the Brigham & Women's and the Dana Farber Cancer Institute in Boston. She has numerous publications and is named on several patents in the cancer drug development field, including novel anti-tubulin agents for advanced solid tumors. She is board certified in Internal Medicine and Hematology.

**Matthew Czajkowski, Chief Financial Officer**

Mr. Czajkowski joined Heat Biologics in May 2013 as its Chief Financial Officer. Prior to joining Heat Biologics, Mr. Czajkowski worked from 2011-2012 as the Chief Executive Officer of NextRay, Inc., a company developing x-ray imaging technology. From 2007 -2010, he served as an independent advisor to various mid stage software and biotech companies where his responsibilities included fundraising. Prior thereto, from 2004-2006, he served as the Chief Financial and Administrative Officer of AAI Pharma Inc. and was part of the work out team for its Chapter 11 filing and from 2000-2004 served as the Chief Financial Officer of Pozen Inc., a publically traded biotechnology company. Prior to this, Mr. Czajkowski was at Goldman, Sachs & Co. where he founded and ran their Asia/Pacific mergers and acquisitions business. Mr. Czajkowski received his MBA from Harvard University in 1983 and his BA from Harvard University in 1977.

**Jennifer Harris, Pharm.D, Vice President of Clinical and Regulatory Affairs**

Dr. Harris is responsible for coordinating the clinical development and operational efforts at Heat Biologics. Dr. Harris has over 20 years of oncology-focused clinical trial experience within the pharmaceutical and biotechnology industries and academic clinical research settings. In 2010 until joining Heat Biologics in 2011, she served as a Medical Science Liaison for Dendreon Corporation, where she was instrumental in coordinating Phase 4 clinical trials of sipuleucel-T (Provenge), the first approved autologous cellular immune therapy to treat prostate cancer. From 2009-2010 while at Novaquest, Dr. Harris lead international, multi-disciplinary teams providing operational trial oversight for early-stage compounds, including protocol development, study report preparation, investigator brochure preparation, regulatory submissions, recruitment of investigator sites, and establishment of clinical trial budgets. From 2006-2008, Dr. Harris was Medical Science Liaison at Celgene Corporation, where she helped conduct multiple clinical trials. She has worked on over 20 IND programs from Phase 1-3, as well as several NDAs.

Dr. Harris received her B.S. and Pharm.D. from the University of North Carolina at Chapel Hill. She has also written multiple clinical publications and meeting abstracts.

**Vadim V. Deyev, M.D., Ph.D., Director of Applied Research**

Dr. Deyev joined Heat Biologics in January 2009 as Director of Applied Research. Prior to joining Heat Biologics, Dr. Deyev worked from 2006-2008 as Associate Scientist of Microbiology and Immunology and Hybridoma and Fusion Protein Core Director at the University of Miami School of Medicine. Working with Dr. Eckhard Podack, Heat Biologics' Scientific Advisor and Chairman of its Scientific Advisory Board, Dr. Deyev has made major contributions to the development of technologies later licensed by the Company. Since 2001, Dr. Deyev has authored numerous publications on immunology and oncology based upon his work with Dr. Podack at the University of Miami. Dr. Deyev joined the team at University of Miami in 1996 until present, after leading the Immunopharmacology Group at the Cancer Research Center in Moscow, Russia. Dr. Deyev received his Ph.D. in Immunology/Oncology from Cancer Research Center in Moscow, Russia and his M.D. from Russian State Medical University.

**John Monahan, Ph.D., Director**

Dr. Monahan is currently the Chief Technology Officer of Synthetic Biologics, Inc., a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Dr. Monahan Co-Founded Avigen Inc. (NASDAQ:AVGN) in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products for the treatment of serious human diseases. Over a 12 year period as CEO of Avigen he raised over \$235M in several private and public financings including its IPO. From 1989-1992, he was VP of R&D at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an Instructor at Baylor College of Medicine, Houston TX. He received his Ph.D. in

Biochemistry in 1974 from McMaster University, Canada and his B.Sc. from University College Dublin, Ireland in 1969. Dr Monahan is a board member of Tacere Therapeutics, CA. He is also a board member of a number of Irish biotech companies including Genable, Cellix, Luxcel, Identigen, Pharmatrin and GK Technologies.

We selected Dr. Monahan to serve on our Board because he brings to the board extensive knowledge of the pharmaceutical and biologics industry. Having served in senior corporate positions in many medical companies he has a vast knowledge of the industry.

**Paul Belsky, M.D., *Director***

Dr. Belsky has served on our Board since November 2009. Dr. Belsky is currently a medical and scientific advisor at Seed-One Ventures and has been a partner at Concorde Medical Group, LLC since June of 1998. Dr. Belsky served as a scientific advisor to Elusys Therapeutics, Sensatex, GenerationOne and TyRx Pharma. Dr. Belsky has extensive expertise in the clinical practice of internal medicine and cardiovascular diseases, and was formerly on the clinical academic faculty at Weill College of Medicine, Cornell University. He is a fellow of the American College of Cardiology and the American College of Chest Physicians, is a member of the American College of Physicians, and a Clinical Assistant Professor of Medicine at New York University School of Medicine. Dr. Belsky received his MD from the University of California at San Francisco, and his AB in Biology from Brown University, where he was elected Phi Beta Kappa.

We selected Dr. Belsky to serve on our Board because he brings to the board extensive knowledge of the medical industry. His medical background aids in the understanding of the detailed science behind our intellectual property.

**Michael Kharitonov, Ph.D., *Director***

Dr. Kharitonov has been the Chief Executive Officer of Voleon Capital Management, an investment management firm, since July 2007 until present. He is a high technology entrepreneur and computer scientist whose areas of expertise include advanced computer and communication technologies and quantitative finance. Dr. Kharitonov is a founder and CEO of Voleon Capital Management LLC. Dr. Kharitonov was a co-founder and former Chairman and CEO of Netli, Inc., a successful Silicon Valley startup that pioneered the development of Application Delivery Networks. Under Dr. Kharitonov's leadership Netli raised over \$20 million in venture financing from a number of Silicon Valley's best known venture capital firms. In 2007 Netli was acquired by Akamai Technologies (NASDAQ: AKAM). Dr. Kharitonov also served as a Vice President of D. E. Shaw and Co., an international investment firm known as one of the most quantitatively advanced and computerized securities trading firms in the world. Dr. Kharitonov holds a Ph.D. degree from the Department of Computer Science at Stanford University. At Stanford he was awarded a Hertz Fellowship and was a winner of several scholarly awards. He also holds a B.A. in Computer Science and Mathematics with highest honors from University of California at Berkeley.

We selected Dr. Kharitonov to serve on our Board because he brings a strong start-up and finance background to the Company, and adds significant strategic, business and financial experience. His prior successful management experience and fundraisings provides him with a broad understanding issues faced by growing companies and of the financial markets and the financing opportunities available to us.

**Edward B. Smith, *Director***

Since April 2005, Mr. Smith has been the Managing Partner of Brightline Capital Management, LLC ("BCM"), a New York-based investment firm founded in 2005. BCM is the investment manager of Brightline Ventures I, LLC, Brightline Ventures II, LLC, Brightline Ventures III, LLC and Brightline Capital Partners, LP. Prior to founding BCM, Mr. Smith worked at Gracie Capital from 2004-2005, GTCR Golder Rauner from 1999-2001 and Credit Suisse First Boston from 1997-1999. Mr. Smith holds a Bachelor of Arts in Social Studies from Harvard College and a Masters in Business Administration from Harvard Business School. He is currently a Director of Z Trim Holdings Inc (OTC:ZTHO), a manufacturer of environmentally friendly agricultural functional ingredients.

We selected Mr. Smith to serve on our Board because he brings a strong business background to the Company, and adds significant strategic, business and financial experience. Mr. Smith's business background provides him with a broad understanding of the issues facing us, the financial markets and the financing opportunities available to us. His service on other public company boards provides him with extensive corporate governance knowledge and insight into issues faced by companies similar to ours.

## **Scientific Advisory Board**

In addition to our Board, we also have a scientific advisory board comprised of six individuals. The Scientific Advisory Board is responsible for providing scientific advice and for assessing the scientific progress of our research and development efforts. We have entered into written agreements and confidentiality agreements with all of our members of our Scientific Advisory Board. The members of our Scientific Advisory Board are compensated for their services. Drs. Allison, Stebbing and Nemunaitis are each entitled to receive \$1,500 per board meeting in addition to a reimbursement for travel and related. In addition, Drs. Allison, Stebbing and Von Hoff each received options to purchase 15,000 shares of our common stock, which options vest over a four year period. Dr. Von Hoff is entitled to receive \$4,000 per onsite advisory board meeting, \$2,000 per telephonic meeting and an hourly rate of \$500 per hour for consultative discussions with management. Dr. Podack receives consulting fees equal to \$3,125 per month subject to increase to \$4,167 per month.

### **Eckhard Podack, M.D., Ph.D., *Scientific Advisor and Chairman, Scientific Advisory Board***

Dr. Podack, the inventor of the Company's technology, serves as Chairman of its Scientific Advisory Board. Dr. Podack received his medical degree from the Johan Wolfgang Goethe University in Frankfurt in 1968 and his Medical License in 1970. Following service in the German Army as Captain and Battalion Physician, he completed his Ph.D. in the field of Biochemistry at the Georg August University in Gottingen. From 1974-1984 he studied Immunology at the Scripps Clinic and Research Foundation in La Jolla CA where he received an Established Investigatorship from the American Heart Association. Dr. Podack is the discoverer of Perforin and well recognized as the "Father" of the field of core forming proteins. Dr. Podack is the Sylvester Distinguished Professor of Microbiology & Immunology and Medicine and Chairman of the Department of Microbiology at the University of Miami, Miller School of Medicine.

### **James Allison, Ph.D., *Scientific Advisor***

Dr. Allison is a leader in the field of immunology, particularly in developing ways to help the immune system recognize and destroy cancer cells. His research is focused on the mechanisms that regulate the immunological response of T lymphocytes, especially strategies to manipulate those responses in clinically relevant areas, including autoimmunity, allergies, vaccinations, and tumor therapy. Dr. Allison is Chairman of the Immunology Program, Director of the Ludwig Center for Cancer Immunotherapy, Attending Immunologist, and David H. Koch Chair in Immunologic Studies at Memorial Sloan-Kettering Cancer Center in New York City.

### **Sol Barer, Ph.D., *Scientific Advisor***

Dr. Barer is the former Chairman and Chief Executive Officer of Celgene Corp., a global biopharmaceutical company engaged in the discovery, development, and commercialization of novel therapies for the treatment of cancer and inflammatory diseases. Dr. Barer has spent the last 20 years with Celgene and its predecessor, Celanese Research Company, serving as President, COO, CEO, Senior Vice President of Science and Technology, and Vice President/General Manager of the Chiral Products Division. Dr. Barer received his B.S. from Brooklyn College and his Ph.D. in organic chemistry from Rutgers University.

### **John Nemunaitis, M.D., *Scientific Advisor***

Dr. Nemunaitis is an oncologist and Executive Medical Director of the Mary Crowley Cancer Research Centers (MCCRC) and has been exploring novel targeted therapies for treating cancer patients for over 20 years. Dr. Nemunaitis received his B.A. and M.D. degrees from Case Western Reserve University. He completed his residency at Boston City Hospital and then performed his Hematology and Oncology fellowship at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle from 1988 to 1993. Dr. Nemunaitis came to Dallas in 1993 to establish the clinical research program for Texas Oncology Physicians Association (TOPA). He later established a not-for-profit translational research program (the MCCRC). He is a committee member of the Western Institutional Review Board (WIRB) and recently co-founded a molecular therapeutic/vaccine biotechnology company with GMP manufacturing capacity called Gradalis, Inc. Dr. Nemunaitis has authored over 250 peer-reviewed publications and 36 book chapters. He has instituted study establishment of over 350 trials, overseen FDA sponsored experimental treatment of nearly 4,000 cancer patients at MCCRC, and has carried out 14 government regulatory (FDA, RAC) presentations for biotechnology product development. He is also developer and holder of 8 new molecular and vaccine Investigational New Drug Applications (IND's). His research focus is clinical in orientation and involves determination of molecular signals in order to optimize targeted therapy, development of RNAi based therapeutics, and cancer vaccine approaches.

**Justin Stebbing, M.D., MA, FRCP, FRCPath, Ph.D., *Scientific Advisor***

Dr. Stebbing is a member of the Royal College of Physicians, American Board of Internal Medicine and a Fellow of the Royal College of Pathologists. Originally, Justin trained in medicine at Trinity College Oxford, obtaining a triple first class degree. After completion of junior doctor posts in Oxford, he undertook a residency (junior doctor) training at The Johns Hopkins Hospital in the US, before returning to London to continue his training in oncology at The Royal Marsden. Justin then undertook a PhD, funded by the Medical Research Council, investigating the interplay between the immune system and cancer. Specifically, the role of heat shock proteins in viral infections and tumorigenesis were examined helping in the development of vaccines that are currently in clinical trials. Dr. Stebbing has published over 300 peer-reviewed papers in journals such as the Lancet, New England Journal, Blood, PNAS, The Journal of Clinical Oncology and Annals of Internal Medicine, the majority as first or last author, as well as over 100 book chapters. His publications mainly focus on early and late stage trials of new drugs, mechanisms of disease, and prognostic indicators. He is on the scientific advisory board of a number of biotechnology companies and the editorial board of a number of world-leading journals such as the Journal of Clinical Oncology. He is now a senior lecturer at Imperial College, London.

**Daniel D. Von Hoff, M.D., *Scientific Advisor***

Daniel D. Von Hoff, M.D., is currently Physician in Chief and Director of Translational Research at TGen (Translational Genomics Research Institute) in Phoenix, Arizona. He is also Chief Scientific Officer for Scottsdale Healthcare's Clinical Research Institute and Scientific Medical Officer for US Oncology. He holds an appointment as Clinical Professor of Medicine, University of Arizona, College of Medicine. Dr. Von Hoff's major interest is in the development of new anti-cancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many of the agents that are now used routinely, including: mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine, lapatinib and others. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies particularly for patients with advanced pancreatic cancer. Dr. Von Hoff has published more than 559 papers, 134 book chapters and over 1,000 abstracts.

Dr. Von Hoff served as an appointee to President Bush's National Cancer Advisory Board from June 2004 to March 2010. Dr. Von Hoff is the past President of the American Association for Cancer Research (the world's largest cancer research organization), a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (acquired by Genzyme after Ilex had 2 agents, alemtuzumab and clofarabine approved for patients with leukemia). He is founder and the Editor Emeritus of Investigational New Drugs – The Journal of New Anticancer Agents; and, Editor-in-Chief of Molecular Cancer Therapeutics. He is also proud to have been a mentor and teacher for multiple medical students, medical oncology fellows, graduate students, and post-doctoral fellows. He is a co-founder of the AACR/ASCO Methods in Clinical Cancer Research Workshop. Dr. Von Hoff currently serves as Physician in Chief for the Translational Genomics Research Institute (TGen) in Phoenix, Arizona and Chief Scientific Officer of Scottsdale Healthcare and US Oncology. Dr. Von Hoff received his MD degree from Columbia University.

**Size of Board**

Our Third Amended and Restated Certificate of Incorporation provides that the number of directors that constitute our whole board of directors on the date on which the first shares of Series B Preferred Stock were issued shall be not less than seven (subject to vacancies which may be filled stockholders having rights to nominate a director to fill such vacancy) and thereafter shall be fixed in accordance with our bylaws which provide that such number shall be determined from time to time by resolution of the Board. Our Board is currently comprised of five board members, leaving two vacancies. The Third Amended and Restated Certificate of Incorporation provides so long as any shares of Series 1 Preferred Stock remain outstanding, the holders of the Series 1 Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series A remain outstanding, the holders of the Series A Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series B Preferred Stock remain outstanding, the holders of the Series B Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series 1 Preferred Stock remain outstanding, the holders of the Series 1 Preferred Stock and the holders of the common stock voting as single class on an as converted basis have the right to elect two directors, the holders of the common stock and Preferred Stock voting together as a single class on an as converted basis are entitled to elect one director; and the holders of the common stock are entitled to elect one director exclusively as a separate class.

## **Committees of the Board of Directors**

Our common stock has been approved for listing on the NASDAQ Capital Market upon completion of this offering. Under the rules of NASDAQ, independent directors must comprise a majority of a listed company's board of directors within twelve months of the completion of an initial public offering. In addition, the rules of The NASDAQ Stock Market require that: (i) on the date of the completion of the offering, at least one member of each of a listed company's audit, compensation and nominating and corporate governance committees be independent; (ii) within 90 days of the date of the completion of the offering, a majority of the members of such committees be independent; and (iii) within one year of the date of the completion of the offering, all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of The NASDAQ Stock Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our Board has determined that Dr. Belsky, Dr. Kharitonov, Dr. Monahan and Mr. Smith, representing four of our five directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The NASDAQ Stock Market. In making this determination, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. We intend to comply with the other independence requirements for committees within the time periods specified above.

We currently have: (i) an audit committee comprised of Dr. Monahan, Mr. Smith, and Mr. Wolf, two of whom are deemed to be independent in accordance with the NASDAQ definition of independence as well as qualify as "audit committee financial experts" as that term is used in Section 407 of Regulation S-K; (ii) a compensation committee comprised of Dr. Belsky, Dr. Monahan and Dr. Kharitonov, each of whom is deemed to be independent in accordance with the NASDAQ definition of independence; and (iii) a nominating and corporate governance committee comprised of Dr. Belsky, Dr. Kharitonov and Mr. Smith. Dr. Monahan and Mr. Smith are deemed to be independent in accordance with the NASDAQ definition of independence. Dr. Monahan and Mr. Wolf qualify as "audit committee financial experts" as that term is used in Section 407 of Regulation S-K.

## ***Leadership Structure***

Our Chief Executive Officer also serves as our Chairman of the Board. Our Board does not have a lead independent director. Our board of directors has determined its leadership structure was appropriate and effective for us given our stage of development.

## 2012 Director Compensation

### Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2012 regarding the compensation of our directors who at December 31, 2012 were not also named executive officers.

Name	Fees Earned or Paid in Cash	Option Awards(1)	Other Compensation	Total
Paul Belsky, MD	\$ —	\$ 1,600	\$ —	\$ 1,600
Michael Kharitonov, Ph.D.	\$ —	\$ 2,134	\$ —	\$ 2,134
John Monahan, Ph.D.	\$ —	\$ 2,134	\$ —	\$ 2,134
Edward Smith	\$ —	\$ 1,600	\$ —	\$ 1,600

- (1) The amounts in the "Option Awards" column reflect the dollar amounts recognized as compensation expense for the financial statement reporting purposes for stock options for the fiscal year ended December 31, 2012 in accordance with SFAS 123(R). The fair value of the options was determined using the Black-Scholes model.

Commencing after this offering, directors who are not employees will receive an annual cash fee of \$15,000 as well as a cash fee of \$5,000 for each committee on which they serve. Upon election to the Board, each non-employee director receives a grant of stock options exercisable for 21,740 shares of common stock vesting over four years having an exercise price equal to the fair market value of the common stock on the date of the grant.



## EXECUTIVE COMPENSATION

Set forth below is the compensation that was paid to all executive officers during the years ended December 31, 2012 and December 31, 2011 that exceeded \$100,000.

### Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Options	Other(1)	Total
Jeffrey Wolf	2012	\$ 250,000	\$ 58,333(2)	\$ 11,492	\$ 11,156	\$ 330,981
<i>Chairman &amp; CEO</i>	2011	\$ 98,147	\$ —	\$ 22,984	\$ 11,370	\$ 132,501
Jennifer Harris	2012	\$ 142,904	\$ —	\$ 2,134	\$ —	\$ 145,038
<i>Vice President of Clinical and Regulatory Affairs</i>	2011	\$ 9,808	\$ —	\$ —	\$ —	\$ 9,808

(1) Represents payment for health insurance

(2) This bonus has been accrued, but to date has yet to be paid.

### Outstanding Equity Awards At Fiscal Year-End (December 31, 2012)

Name and Principal Position	Number of securities underlying unexercised options/exercisable	Number of securities underlying unexercised options/unexercisable	Option exercise price	Option expiration date
Jeffrey Wolf	10,965	—	\$ 2.30	12/17/2019
<i>Chairman of the Board, Chief Executive Officer</i>	108,696	—	\$ 0.71	4/7/2016
Jennifer Harris	21,740	—	\$ 0.64	12/1/2022
<i>Vice President of Clinical and Regulatory Affairs</i>	—	—	—	—

Note: We use the Black-Scholes option-pricing model to value all options issued by the Company.

### Employment Agreements

On December 18, 2009, we entered into an employment agreement with Jeffrey Wolf to act as our Chief Executive Officer, which was amended on November 22, 2011. Mr. Wolf receives an annual base salary of \$250,000 per year. In addition, Mr. Wolf was entitled to receive an annual bonus of at least \$25,000 after his first year of service, \$50,000 after his second year of service and \$75,000 after his third year of service. He also may receive, at the sole discretion of the board, additional performance-based bonuses equal to up to 50% of this then outstanding base salary at the end of each year. Upon execution of the agreement, Mr. Wolf was issued options exercisable for 119,661 shares of our common stock. In addition, he is to receive certain options to purchase 2% of our fully diluted equity at an exercise price equal to the then current market price if our stock is traded on a nationally recognized exchange or NASDAQ and our market capitalization is at least \$250 million for at least 5 days.

If Mr. Wolf's employment contract is terminated for death or disability (as defined in the agreement), he (or his estate in the event of death) will receive six month's severance. If Mr. Wolf's employment is terminated by us other than for cause, he will receive twelve months severance. In addition, if Mr. Wolf's employment is terminated by us other than for cause all Restricted Shares, common stock and options to purchase common stock that would have vested shall immediately vest. Mr. Wolf will not be entitled to any additional severance in the event he is terminated for cause or voluntarily resigns. Under his employment agreement, Mr. Wolf has also agreed to non-competition provisions.

On June 10, 2008, Mr. Wolf purchased 260,870 shares of our common stock, at a purchase price of \$0.0002 per share. Seed-One Holdings VI, LLC and Safeway Medical, LLC, investment funds of which Mr. Wolf is a managing member also purchased 656,427 and 434,783 shares of our common stock, respectively, on June 10, 2008 at a purchase price of \$0.0002 per share. In addition, Mr. Wolf purchased 2,622 shares of our Series B Preferred Stock in our recent private placement that together with accrued dividends thereon will convert to 1,150 shares of common stock upon consummation of this offering and he will be issued an additional 46 shares of common stock upon consummation of this offering in lieu of Series B-2 Preferred Stock that Mr. Wolf has committed to purchase upon our receipt of certain grant funding and the shares underlying the warrants to be issued at such time.

On May 15, 2013, we entered into an employment agreement with Matthew E. Czajkowski to act as our Chief Financial Officer. Mr. Czajkowski receives an annual base salary of \$105,000 per year for his provision of services to us for fifty-percent of his professional time. In addition, Mr. Czajkowski may receive, at the sole discretion of the board, additional performance-based bonuses equal to up to 50% of this then outstanding base salary at the end of each year. Upon execution of the agreement, Mr. Czajkowski was issued options exercisable for 38,364 shares of our common stock, which options are exercisable over a ten year period and vest monthly over three years at an exercise price of \$8.81 per share. Upon reaching full-time employment status, he will be entitled to all benefits to which our other executive officers are entitled. If Mr. Czajkowski's employment contract is terminated by the board of directors not for cause (as defined in the agreement) he (or his estate in the event of death) will receive three month's severance. If Mr. Czajkowski's employment contract is terminated for death or disability (as defined in the agreement), he (or his estate in the event of death) will be entitled to receive all unpaid compensation up to such date of termination and such number of options that would have vested upon the date of termination will immediately vest. Under his employment agreement, Mr. Czajkowski has also agreed to customary non-competition provisions.

In November 2011, we entered into an employment agreement with Jennifer Harris to act as our Senior Director of Clinical Development. Ms. Harris received a base salary of \$150,000 and ten year options exercisable for 21,740 shares of common stock at an exercise price of \$0.64 per share. In May 2013, Ms. Harris' employment agreement with us was amended due to her reduced work schedule and her salary was reduced to \$75,000. Ms. Harris was granted 8,696 additional options that will vest over four years and are exercisable at \$8.81 per share.

## DESCRIPTION OF OUR SECURITIES

### General

The following is a summary of the rights of our common stock and Preferred Stock and related provisions of our articles of incorporation and bylaws. For more detailed information, please see our articles of incorporation and bylaws.

We are authorized to issue 50,000,000 shares of common stock, par value \$0.0002 per share, of which 1,861,869 shares are outstanding and 10,000,000 shares of Preferred Stock, par value \$0.0001 per share, of which 112,500 shares are designated Series 1 Preferred Stock and are outstanding and are currently convertible into 49,960 shares of common stock, 2,000,000 shares are designated Series A Preferred Stock and 1,863,128 shares are outstanding and are currently convertible into 810,057 shares of common stock, 4,100,000 are designated as Series B-1 Preferred Stock and 1,891,419 shares are outstanding including accrued dividends and are currently convertible into 828,889 shares of common stock and 2,000,000 are designated Series B-2 Preferred Stock. In addition, upon consummation of a Qualified Public Offering, the investors of our Series B-1 Preferred Stock will be issued an aggregate of 32,879 shares of common stock (assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus), and our obligation to issue, and the investors obligation to purchase, Series B-2 Preferred Stock and warrants upon fulfillment of the conditions specified in our Stock Purchase Agreement with the investors will terminate.

### Common Stock

#### *Reverse Stock Split*

On May 29, 2013, we effected a 1-for-2.3 reverse stock split. Upon the effectiveness of the reverse stock split, every 2.3 shares of outstanding common stock decreased to one share of common stock. Similarly, the number of shares of common stock into which each outstanding option and warrant to purchase common stock is exercisable decreased on a 1-for-2.3 basis and the exercise price of each outstanding option and warrant to purchase common stock increased proportionately. In addition, the applicable conversion price of the Preferred Stock was proportionately increased to adjust for the stock split resulting in a proportionate decrease in the number of shares to be issued upon conversion of the Preferred Stock.

Unless otherwise indicated, all references to share numbers in this prospectus filed as part of this registration statement reflect the effects of these reverse stock splits.

The holders of our common stock are entitled to one vote per share on all matters to be voted on by the shareholders. Subject to preferences that may be applicable to any outstanding shares of Preferred Stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the Board out of funds legally available therefore. If we liquidate, dissolve or wind up, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of Preferred Stock. Holders of common stock have no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are, and all shares of common stock to be outstanding upon completion of this offering will be, fully paid and nonassessable. Except as otherwise required by Delaware law, and subject to the rights of the holders of Preferred Stock described below to elect certain directors and vote on an as converted basis together with the holders of the common stock, all stockholder action, other than the election of directors, is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy. The election of directors by our stockholders, subject to the rights of the holders of Preferred Stock described below to elect certain directors, is determined by a plurality of the votes cast by the stockholders entitled to vote at any meeting held for such purposes at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy.

### Representative's Warrants

We are registering the warrants (and the shares of common stock underlying such warrants) we have agreed to sell to Aegis Capital Corp. (the representative of the underwriters in this offering) to purchase up to a total of 113,636 shares of common stock (5% of the shares sold in this offering). See "Underwriting—Representative's Warrants" beginning on page 103 of this prospectus for a description of these warrants.

## **Preferred Stock**

### **Series 1, Series A, Series B**

Our Board has the authority, without further action by the shareholders, to issue from time to time the Preferred Stock that remains unissued, all of which has been designated as either Series 1 Preferred Stock or Series A Preferred Stock, which has rights, preferences, privileges and restrictions which are greater than or senior to the rights of the common stock. The issuance of Preferred Stock could adversely affect the voting power of holders of common stock and reduce the likelihood that such holders will receive dividend payments and payments upon liquidation. Such issuance could have the effect of decreasing the market price of the common stock. The issuance of Preferred Stock or even the ability to issue Preferred Stock could have the effect of delaying, deterring or preventing a change in control.

### **Automatic Conversion**

Each share of Preferred Stock automatically converts to common stock upon the earlier to occur of (i) on the date of consummation of a sale of common stock in a firm commitment underwritten public offering resulting in aggregate net cash proceeds to the Company (after deducting applicable underwriting discounts and commissions) of at least \$15 million net proceeds; (ii) with respect to the Series A Preferred Stock, if 2/3 of the Series A Preferred Stock holders (including one of the larger investors so long as they hold 40% of the Series A Preferred Stock) vote in favor of a conversion then the Series A will automatically convert to common stock; (iii) with respect to the Series 1 Preferred Stock, if 2/3 of the Series 1 Preferred Stock holders vote in favor of a conversion then the Series 1 will automatically convert to common stock; and (iv) with respect to the Series B Preferred Stock if 2/3 of the Series B Preferred Stock holders vote in favor of a conversion then the Series B will automatically convert to common stock. However, if we do not raise net proceeds of \$15,000,000 in this offering, or the holders of shares do not vote in favor of conversion, then the Series 1, Series A, Series B-1 and Series B-2 Preferred Stock will not automatically convert to common stock and will remain outstanding.

### **Optional Conversion**

The preferred stock is convertible into common stock at the option of the holder at any time. The conversion ratio for each share of the Series 1 Preferred Stock and the Series A Preferred Stock is its Original Issue Price (\$2.35 and \$2.10 for each share of the Series 1 Preferred Stock and Series A Preferred Stock, respectively) divided by its Conversion Price, as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like, which Conversion Price initially was the Original Issue Price. The conversion ratio for each share of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock is its Original Issue Price (\$2.67 and \$5.00 for each share of the Series B-1 Preferred Stock and Series B-2 Preferred Stock, respectively) plus accrued but unpaid dividends thereon divided by its conversion price, as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like, which conversion price initially was the Original Issue Price.

In the event we at any time or from time to time after the Initial Series B Issuance Date shall issue additional shares of common stock without consideration or for consideration per share less than the Series 1 Conversion Price, Series A Conversion Price, Series B-1 Conversion Price, or Series B-2 Conversion Price, in effect on the date of and immediately prior to such issue, then the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, Series B-2 Conversion Price, shall be reduced, to a price determined by multiplying the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price in effect by a fraction, (A) the numerator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of shares of common stock which the aggregate consideration received by us for the total number of Additional Shares of Common Stock so issued would purchase at the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price, as in effect immediately prior to such issuance, and (B) the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of such Additional Shares of common stock so issued. To date no such adjustment has occurred.

## Dividends

The Series B Preferred Stock has a priority with respect to dividend distributions and distributions upon liquidation. The Series B Preferred Stock receive dividends when and as and if declared by our Board at a rate of 5% of their original issue price (the "Original Issue Price") of such shares which is \$6.14 per share for the Series B-1 Preferred Stock and \$11.50 per share for the Series B-2 Preferred Stock. If we declare or pay a dividend upon the common stock, we must also pay to the holders of the Series A, 1 and B Preferred Stock the dividends that would have been declared with respect to common stock issuable upon conversion of the Series A, 1 and B Preferred Stock; provided, however that we cannot declare or pay a dividend unless and until all accrued dividends on the Series B Preferred Stock have been paid.

## Liquidation

In the event of a liquidation, the holders of the Series B-1 and B-2 Preferred Stock are entitled to receive before any payment to any other Preferred Stockholder or common stock holder and *pari passu* with the holders of the Series 1 Preferred Stock an amount per share equal to the greater of \$6.14 for the Series B-1 Preferred Stock and \$11.50 for the Series B-2 Preferred Stock plus any dividends accrued and unpaid whether or not declared. After payment in full of the Series B Preferred Stockholders the holders of the Series A Preferred Stock are entitled to receive before any payment to the common stock holder and *pari passu* with the holders of the Series 1 Preferred Stock an amount per share equal to \$4.83 plus any dividends declared but unpaid. In the event of a liquidation, the holders of the Series 1 Preferred Stock are entitled to receive before any payment to the common stock holder and *pari passu* with any distribution to the Series A Preferred Stock an amount per share equal to \$5.41 plus any dividends declared but unpaid. After the payment in full of the amounts set forth above, our assets will be distributed ratably to all holders of common stock and Series B Preferred Stock on an as converted basis except that the Series B Preferred Stockholders shall not continue to share in such distribution after each has received 3 times its Original Issue Price.

## Voting Rights

Each holder of Preferred Stock is entitled to vote on all matters stockholders are entitled to vote and to cast the number of votes as shall equal the whole number of shares of common stock into which their shares of Preferred Stock are convertible. The Third Amended and Restated Certificate of Incorporation provides that so long as any shares of Series 1 remain outstanding, the holders of the Series 1 Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series A Preferred Stock remain outstanding, the holders of the Series A Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series B Preferred Stock remain outstanding, the holders of the Series B Preferred Stock voting as single class have the right to elect one director; so long as any shares of Series 1 Preferred Stock remain outstanding, the holders of the Series 1 Preferred Stock and the holders of the common stock voting as single class on an as converted basis have the right to elect two directors, the holders of the common stock and Preferred Stock voting together as a single class on an as converted basis are entitled to elect one director; and the holders of the common stock are entitled to elect one director exclusively as a separate class. All of the rights set forth in the preceding sentence terminate upon consummation of a firm commitment underwritten public offering with net proceeds to us of at least \$15,000,000 and following such event the Preferred Stock will have no voting rights except as otherwise required by law. Except as otherwise required by Delaware law, and subject to the rights of the holders of Preferred Stock described above to elect certain directors and vote on an as converted basis together with the holders of the common stock, all stockholder action other than the election of directors is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy. The election of directors by our stockholders, subject to the rights of the holders of Preferred Stock described above to elect certain directors, is determined by a plurality of the votes cast by the stockholders entitled to vote at any meeting held for such purposes at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or proxy.

## Protective Provisions

The Third Amended and Restated Certificate of Incorporation provides that at any time the Preferred Stock is outstanding the following actions cannot be taken without the consent of at least a majority of the Series B Preferred Stock, at least a majority of the Series A Preferred Stock (which majority must include Brightline Ventures III LLC or its affiliates for so long as Brightline Ventures III LLC holds at least 40% of the Series A Preferred Stock), at least a majority of the Series 1 Preferred Stock and at least a majority of the common stock, each voting as a separate class:

- (i) amend, alter or repeal any provisions of the Third Amended and Restated Articles of Incorporation or bylaws, unless in connection with a Qualified Public Offering;
- (ii) create, or issue any additional classes of capital stock unless the same ranks junior to the Series A Preferred Stock in terms of dividends and liquidation or increase the number of authorized shares of the Series A Preferred Stock or any other class of stock unless it ranks junior to the Series A Preferred Stock in terms of dividends and liquidation, unless in connection with a Qualified Public Offering;
- (iii) reclassify, alter or amend any existing security that is *pari passu* with the Series A Preferred Stock in terms of dividends or liquidation if such reclassification would render it senior to the Series A Preferred Stock or reclassify any stock junior to the Series A Preferred Stock in terms of dividends or distributions if such reclassification would render it senior to or *pari passu* with the Series A Preferred Stock, unless in connection with a Qualified Public Offering;
- (iv) purchase or redeem or pay or declare any dividend or make any distribution on shares other than as approved by the Board, repurchases of stock of certain former employees, officers or directors or consultants, dividends payable solely in the form of additional shares of stock, unless in connection with a Qualified Public Offering;
- (v) Take any action to dissolve or otherwise liquidate the Company; or
- (vi) Sell all or substantially all of our assets or effect a merger or consolidation unless the Series A Preferred would receive three (3) times their initial investment.

The Third Amended and Restated Certificate of Incorporation also provides that for so long as a majority of the originally issued shares of Series B Preferred Stock remain outstanding and until we receive \$20,000,000 through a financing, grant or licensing or joint venture agreement or we cannot without approval of holders of a majority of the Series B Preferred Stock voting as a single class:

- (i) operate any business other than our business as carried out on the original date shares of Series B-1 Preferred Stock were issued;
- (ii) make a loan to any entity or subsidiary other than an 80% owned subsidiary;
- (iii) dispose or acquire an interest in a business other than under specified circumstances;
- (iv) enter into a joint venture or make an investment in excess of \$5,000,000;
- (v) make or commit to make an expenditure of \$5,000,000 or more;
- (vi) make a loan of in excess of \$5,000;
- (vii) issue debt in excess of \$5,000,000 other than under existing agreements;
- (viii) approve an annual business plan.

Each holder of Preferred Stock has a right to convert each share of its stock into one share of common stock; however such number is adjusted in certain cases including if we issue convertible securities at a price lower than that paid by the Preferred Stockholders.

All of the protective provisions automatically terminate upon consummation of a firm commitment underwritten public offering with gross proceeds to us of at least \$15,000,000 and following such event the Preferred Stock will have no voting rights except as otherwise required by applicable law.

## Registration Rights

At any time after the earlier of the: (i) March 25, 2014; (ii) 180 days after the closing of an initial public offering; (iii) the completion by us of a merger, consolidation, sale, transfer, lease or other conveyance of all or substantially all of the assets or any other similar business combination or transaction with another company listed on the New York Stock Exchange, the NYSE MKT, the NASDAQ National Market or the NASDAQ SmallCap Market; or (iv) the date upon which we become a reporting company under Section 12 or 15 of the Exchange Act other than in connection with the our initial public offering, (1) the holders of Series B Preferred Stock have two demand registration rights upon written request by holders of at least 50% of the then outstanding Registrable Securities (as

defined below) attributable to or originally attributable to the Series B Preferred Stock, or a lesser percentage if the anticipated aggregate offering price of the Registrable Securities requested to be included in any such registration is at least \$5,000,000 and (2) the holders of Series 1 and Series A Preferred Stock have two demand registration rights upon written request by holders of at least 50% of the Registrable Securities not attributable or originally attributable to the Series B Preferred Stock. The holders of the Series 1, Series A and Series B Preferred Stock have unlimited piggyback registration rights and unlimited registrations on Form S-3 so long as the aggregate offering price to the public of Registrable Securities proposed to be included in such registration is not less than \$1,000,000. Registrable Securities is defined as the shares of common stock: (i) issued or issuable upon conversion of Series 1, Series A and Series B Preferred Stock; (ii) held or deemed held by the holders of the Series 1, Series A and Series B Preferred Stock pursuant to rights of first refusal or other purchase rights; (iii) issued in connection with the exercise of any warrants granted to the Series 1, Series A and Series B Preferred Stockholders; and (iv) issued or issuable as a dividend or other distribution on such shares of common stock. Registrable Securities do not include any securities: (i) sold by a person to the public either pursuant to a registration statement or Rule 144; (ii) sold in a private transaction in which the transferor's rights are not assigned or properly assigned; or (iii) that are eligible for sale without restriction under Rule 144. In addition, the shares underlying the warrant issued to Square 1 Bank are entitled to piggy-back registration rights.

#### **Other Rights**

The holders of Series B Preferred Stock have certain preemptive right, rights of first refusal, co-sale and tag along rights, all of which automatically terminate upon consummation of a firm commitment underwritten public offering with net proceeds to us of at least \$15,000,000.

#### **Warrants and Stock Options**

##### *Warrants*

In March 2011, we granted warrants exercisable for an aggregate of 32,610 shares of our common stock to 5 individuals for services rendered in connection with a placement agency agreement we had with Paramount BioCapital, a company no longer in existence. The warrants are exercisable at \$0.48 per share, vest immediately upon exercise, contain a cashless exercise feature and expire on March 21, 2021.

In December 2011, we issued a warrant, which as amended, exercisable for 12,940 shares of our Series A Preferred Stock to the North Carolina Biotechnology Center in connection with a loan. This warrant will be converted to the right to purchase common stock at the time of the offering. The warrant is exercisable for a period of ten years at a price per share of \$4.83, contains a cashless exercise feature and contains a weighted average price adjustment feature.

In August 2012, we issued a warrant, which as amended, is exercisable for 17,500 shares of our common stock to Square 1 Bank in connection with our loan from them which after adjustments for our 1-for-2.3 stock split will be convertible into 7,609 shares of common stock. The warrant is exercisable for a period of ten years at a price per share of \$4.83, contains a cashless exercise feature and contains a weighted average price adjustment feature. If not exercised before the expiration date of the warrant, the warrant shall be deemed to have been exercised on a cashless basis. With respect to any offering conducted at least twelve months after this offering, the holder of the warrant is entitled to piggyback registration rights with respect to the underlying shares. If we request and Square 1 Bank makes Tranche A Term Loans in an aggregate amount in excess of \$1,000,000 then the number of shares for which the warrant is exercisable automatically increases by 25,357. If we issue securities with a per share price less than the warrant price of \$4.83, the number of shares of common stock issuable upon exercise of the warrant is adjusted as provided in our Certificate of Incorporation for our Series A Preferred Stock.

In March 2013, we consummated the first tranche of our private placement of our Series B Preferred Stock. In addition to issuing Series B-1 Preferred Stock to investors in the offering, we agreed, at the second tranche closing, to issue to each investor, upon their payment for Series B-2 shares that they have committed to acquire, which is conditioned upon our receipt of certain grant funding, we will issue to each such investor a warrant exercisable for two shares of Series B-1 Preferred Stock for each share of Series B-2 Preferred Stock purchased by such investor at the second tranche closing.

### *Stock Incentive Plan*

Pursuant to the terms of our 2009 Stock Incentive Plan, as amended (the "Plan"), we are authorized to grant up to 869,565 awards in the form of options, restricted stock, restricted stock units and other stock based awards exercisable to officers, directors, employees and consultants. As of May 21, 2013, we have issued and outstanding under the Plan options exercisable for 662,543 shares of common stock to a total of 25 individuals and entities for services rendered. Of such amount as of May 21, 2013, 459,326 options had vested and were exercisable, 203,195 options will vest subsequent to May 21, 2013.

In 2009, we issued options for an aggregate of 65,314 shares of our common stock to 5 individuals. As of May 21, 2013, all options have vested and 34,783 had been terminated. Of the vested options exercisable, 19,661 have an exercise price of \$2.30 and expire in 2019 and 10,870 have an exercise price of \$0.0002 and expire in 2019.

In 2010, we issued options exercisable for an aggregate of 78,266 shares of our common stock at an exercise price of \$0.58 per share that expire in 2020 to 9 individuals. As of May 1, 2013, 46,740 of such options had vested and were exercisable and 21,740 had vested and been exercised. The remaining unvested shares of 9,786 will vest by September of 2014.

In 2011, we issued options for an aggregate of 334,031 shares of common stock, of which 8,696 shares had terminated resulting in 325,335 options exercisable as of May 21, 2013. As of May 21, 2013, 268,261 shares of such options vested and were exercisable (of which 159,566 shares of common stock at an exercise price of \$0.64 per share that mature in 2020 and 2021 were issued to 11 individuals and options exercisable for an aggregate of 108,696 shares of our common stock at an exercise price of \$0.71 per share that mature in 2019 were issued to one individual). The remaining unvested options of 57,073 will vest at various periods over the next three years at an exercise price of \$0.64 per share.

In 2012, we issued options exercisable for an aggregate of 178,742 shares of our common stock at an average exercise price of \$0.76 per share that mature in 2022 to 6 individuals and 2 entities. As of May 21, 2013, 113,796 of such options vested and were exercisable and 1,087 had been exercised. The remaining unvested shares of 63,859 vest over the next four years.

In 2013, we issued options exercisable for an aggregate of 72,496 shares of our common stock at an average exercise price of \$8.81 per share that mature in 2023 to 8 individuals. As of May 21, 2013, 2,132 of such options vested and were exercisable. The remaining unvested shares of 70,364 vest over the next two to four years.

### **Convertible Notes**

In September 2011, convertible notes in the principal amount of \$2,623,709 were converted into shares of Series A Preferred Stock, of which notes in the principal amount of \$2,273,709 were issued to an investor, the managing member of which is Mr. Smith, a member of our Board. Of such notes, three convertible promissory notes in the aggregate principal amount of \$1,447,709 were issued in 2011 to two different note holders and the remaining notes in the aggregate principal amount of \$1,176,000 were issued to two investors in 2010. The notes accrued interest at a rate of 3% per annum and were scheduled to mature 18 months after issuance.

In October 2011, in connection with our manufacturing service agreement, we issued a convertible promissory note to our manufacturer, of which \$197,099 was outstanding as of December 31, 2012. As of May 1, 2013, 694,478.96 was due such vendor. The note has been extinguished and the payment date for all outstanding payables, including those previously due under the terms of the Note, has been extended until the earlier of July 15, 2013 or this offering or any other financing in which we receive gross proceeds of \$2,500,000. If the closing of such financing does not occur prior to July 15, 2013 then one half of the payables owed as of July 15, 2013 shall be due July 15 2013 and the balance shall remain payable until such a financing is consummated.



## Notes Payable

In December 2011, we entered into a loan agreement with the North Carolina Biotechnology Center for an amount up to \$250,000. The note evidencing the loan matures on December 13, 2014 and bears interest at a rate of 4.25%. The principal is payable in annual installments in the amount of 5% of the outstanding principal commencing on the one year anniversary of the loan and each one year anniversary thereafter. As of August 31 2012, we had repaid all amounts outstanding under the loan.

In August 2012, we entered into a secured loan with Square 1 Bank, the proceeds of which were used in part to pay off the loan from North Carolina Biotechnology Center. The loan and security agreement that we entered with Square 1 Bank in connection with the secured loan (the "Square 1 Agreement") provides that Square 1 Bank will provide us with a term loan in the aggregate principal amount not to exceed \$1,000,000 to be used for working capital and capital expenditures (the "Tranche A Loan"). The Tranche A Loan will be available to us until August 7, 2013. The Tranche A Loan is payable on August 7, 2013 in 36 monthly installments of principal and accrued interest. The Tranche A Loan matures on August 7, 2016. If we receive a grant that provides aggregate funds with a value of \$16,000,000, we may request that the maximum aggregate of the Tranche A Loan and the Tranche B Loan amount increases to \$2,775,000. The Square 1 Agreement, as amended, also provides that if we receive at least \$4,500,000 from the sale of our equity to investors after February 15, 2013 but on or before March 31, 2013 (such date we receive such funds being referred to as the "Trigger Date"), we can borrow an additional term loan in the aggregate principal amount not to exceed \$1,000,000 to be used for working capital and capital expenditures (the "Tranche B Loan"). Due to the closing of the Series B-1 Preferred Stock private placement in March 2013, we will be able to borrow an additional \$1,000,000 under such loan. The Tranche B Loan is payable as interest-only prior to the twelve month anniversary of the Trigger Date month after until August 7, 2013 and thereafter is payable in equal monthly installments of principal plus accrued interest until August 7, 2016. The Tranche B Loan matures on August 7, 2016. The Bank also made one term loan in the amount of \$225,000, which was used to repay our debt to North Carolina Biotechnology Center (the "Term B Loan"). The Term B Loan matures December 14, 2014 and requires payments on the one and two year anniversary of the date of issuance equal to five percent of the principal amount of the loan plus accrued interest, with the balance of the loan being paid on maturity. Once repaid the loans may not be re-borrowed. The loans are secured by a lien on substantially all of our assets, including our stock in our subsidiaries but excluding our intellectual property. Finally, the Bank also made one Non-Formula Advance (the "Non-Formula Advance") in the aggregate principal amount of \$200,000 which was paid in full in 2013. As of May 1, 2013, we had outstanding \$725,000 under the Square 1 Bank loans. Under the loan agreement, as amended, we were required to raise an additional \$4,500,000 on or prior to March 31, 2013. This equity milestone was satisfied and the Company is currently in full compliance with all loan covenants. In connection with the loan, we issued Square 1 Bank a warrant exercisable for 17,500 shares of our common stock which after adjustment for our 1-for-2.3 stock split will be convertible into 7,609 shares of common stock. The warrant is exercisable for ten years at a price of \$4.83 which price is subject to adjustment for certain transactions including certain dilutive transactions.

## SECURITY OWNERSHIP OF MANAGEMENT AND OTHER BENEFICIAL OWNERS

The table below sets forth information as of May 21, 2013 regarding the beneficial ownership of the Company's common stock, Series A Preferred Stock Series 1 Preferred Stock and Series B-1 Preferred Stock as of the date of this prospectus. Beneficial ownership generally includes voting or investment power with respect to securities. The table reflects ownership by:

- \* each person or entity who owns beneficially 5% or greater of the shares of the Company's outstanding common stock;
- \* each of our executive officers and directors; and
- \* our executive officers and directors as a group.

Except as otherwise set forth therein, each stockholder's pre-offering percentage ownership in the following table is as of May 21, 2013 and is based on a total number of 3,583,654 shares comprised of 1,861,869 shares of common stock, 1,975,628 shares of Series A and Series 1 Preferred Stock issued and outstanding that converts to 860,017 shares of common stock, 1,891,419 shares of Series B-1 Preferred Stock issued and outstanding that together with accrued dividends converts to 828,889 shares of common stock and an additional 32,879 shares of common stock that will be issued to investors of our Series B-1 Preferred Stock upon consummation of this offering (assuming an initial public offering price of \$11.00 per share, which is the midpoint of the range set forth in the cover page of this prospectus). All share ownership figures include shares of common stock issued and shares of common stock issuable upon conversion of Preferred Stock issued and shares of common stock issuable upon exercise of options or warrants that had vested as of May 21, 2013 or will vest within 60 days of May 21, 2013, which are deemed outstanding and beneficially owned by such person for purposes of computing his or her percentage ownership, but not for purposes of computing the percentage ownership of any other person. As of May 21, 2013, our Board had authorized a total of 869,565 awards eligible for grant under our 2009 Stock Incentive Plan. As of May 21, 2013, 662,543 options were outstanding.

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 100 Europa Drive, Suite 420, Chapel Hill, North Carolina 27517. Except as otherwise indicated, and subject to applicable community property laws, except to the extent authority is shared by both spouses under applicable law, the Company believes the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Ownership (Pre-Offering)	Percentage Ownership Post-Offering
<b>Executive Officers &amp; Directors(1)</b>			
Paul Belsky, M.D. (Director)(2)	59,064	1.6%	1.0%
Vadim Deyev, MD, Ph.D.(3)	10,870	*	*
Jennifer Harris, Pharm.D(4)	8,153	*	*
Michael Kharitonov, Ph.D. (Director)(5)	69,580	1.9%	1.2%
John Monahan, Ph.D. (Director)(6)	20,816	*	*
Edward Smith (Director)(7)	711,692	19.8%	12.1%
Sandra Silberman, MD, Ph.D.(8)	15,761		
Jeffrey Wolf (Director, CEO, Treasurer & Secretary)(9)	1,353,371	36.5%	22.6%
Matthew E. Czajkowski (CFO)(10)	2,132	*	*
All Executive Officers & Directors, as a group (9 persons)	2,251,439	59.1%	37.0%
<b>5% Stockholders(1)</b>			
Brightline Ventures III, LLC(11)	697,303	19.5%	11.9%
Eckhard Podack M.D., Ph.D.	260,870	7.3%	4.5%
Orion Holdings V, LLC (12)	695,653	19.4%	11.9%
Seed-One Holdings VI, LLC(12)	536,862	15.0%	9.2%
FW Heat Biologics, LLC(13)	447,937	12.5%	7.6%

\*less than 1%

- (1) Unless otherwise set forth below, the mailing address of Executive Officers, Directors and 5% or greater holders is c/o the Company, 100 Europa Drive, Suite 420, Chapel Hill, NC 27517.
- (2) Dr. Belsky has been issued options exercisable for 26,958 shares of common stock, of which 14,389 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Dr. Belsky includes 43,479 shares of common stock. Includes 2,622 shares of Series B Preferred Stock that together with accrued dividends will convert to 1,150 shares of common stock upon consummation of this offering. Includes 46 shares of common stock to be issued upon consummation of this offering in lieu of Series B-2 Preferred Stock that Dr. Belsky has committed to purchase upon our receipt of certain grant funding and the shares underlying the warrants to be issued at such time.
- (3) Dr. Deyev has been issued options exercisable for 10,870 shares of common stock, of which 10,870 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Mr. Deyev.
- (4) Dr. Harris has been issued options exercisable for 30,436 shares of common stock, of which 8,153 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Ms. Harris.
- (5) Includes 112,500 shares of Series 1 Preferred Stock which convert to 49,960 shares of common stock held by Dr. Kharitonov. Dr. Kharitonov disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a – 1(a)(2) promulgated under the Exchange Act) that he may have in the Sunrise Equity, LLC. Dr. Kharitonov has been issued options exercisable for 34,567 shares of common stock, of which 19,620 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Dr. Kharitonov.
- (6) Dr. Monahan has been issued options exercisable for 34,567 shares of common stock, of which 19,620 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Dr. Monahan. Includes 2,622 shares of Series B Preferred Stock, that together with accrued dividends will convert to 1,150 shares of common stock upon consummation of this offering. Includes 46 shares of common stock to be issued upon consummation of this offering in lieu of Series B-2 Preferred Stock that Dr. Monahan has committed to purchase upon our receipt of certain grant funding and the shares underlying the warrants to be issued at such time.
- (7) Mr. Smith has been issued options exercisable for 26,958 shares of common stock, of which 14,389 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Mr. Smith. Includes 1,603,795 shares of Series A Preferred Stock that will convert to 697,303 shares of common stock upon consummation of this offering owned by Brightline Ventures III, LLC, of which Mr. Smith disclaims beneficial ownership except to the extent of any pecuniary interest.
- (8) Dr. Silberman has been issued options exercisable for 19,566 shares of common stock, of which 15,761 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Dr. Silberman.
- (9) Includes 695,653 shares of common stock held by Orion Holdings V, LLC and 536,862 shares of common stock held by Seed-One Holdings VI, LLC, entities for which Mr. Wolf serves as the managing member. Mr. Wolf is deemed to beneficially own the shares held by such entities as in his role as the managing member he has the control over the voting and disposition of any shares held by these entities. Does not include 86,957 shares of common stock beneficially owned by Mr. Wolf's children's trust which Mr. Wolf is not the trustee of. Mr. Wolf disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a – 1(a)(2) promulgated under the Exchange Act) that he may have in such entities. In addition, if our Company is traded on a recognized national exchange or NASDAQ while Mr. Wolf is employed by us and the market capitalization of our Company is in excess of \$250 million for at least five consecutive trading days, then Mr. Wolf will be entitled to receive an additional stock option equal to 2% of the then outstanding shares of our common stock, at an exercise price equal to the then current market price as determined in good faith by the board. Mr. Wolf has been issued options exercisable for 119,661 shares of common stock, of which 119,661 shares are vested and exercisable within 60 days of May 21, 2013 and are included in the beneficial ownership of Mr. Wolf. Also includes 2,622 shares of Series B Preferred Stock, that together with accrued dividends will convert to 1,150 shares of common stock upon consummation of this offering. Includes 46 shares of common stock to be issued upon consummation of this offering in lieu of Series B-2 Preferred Stock that Mr. Wolf has committed to purchase upon our receipt of certain grant funding and the shares underlying the warrants to be issued at such time.
- (10) Mr. Czajkowski has been issued options exercisable for 38,364 shares of common stock, of which 2,132 shares are vested and exercisable within 60 days of May 21, 2013 and included in the number of shares beneficially owned by Mr. Czajkowski.

- (11) Includes 1,603,795 shares of Series A Preferred Stock that will convert to 697,303 shares of common stock upon consummation of this offering. Mr. Smith is deemed to beneficially own these shares. Mr. Smith disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a – 1(a)(2) promulgated under the Exchange Act) that he may have in such entities.
- (12) Mr. Wolf serves as the managing member of such entity. Mr. Wolf is deemed to beneficially own the shares held by such entity as in his role as the managing member he has the control over the voting and disposition of any shares held by this entity. Mr. Wolf disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a – 1(a)(2) promulgated under the Exchange Act) that he may have in such entity.
- (13) Includes 983,146 shares of Series B-1 Preferred Stock that together with accrued dividends will convert to 430,840 shares of common stock upon consummation of this offering. Includes 17,097 shares of common stock to be issued upon consummation of this offering in lieu of Series B-2 Preferred Stock that the entity has committed to purchase upon our receipt of certain grant funding and the shares underlying the warrants to be issued at such time held by FW Heat Investors, L.P., of which FW Heat Genpar, LLC is the sole general partner. Jay Hebert is the sole member of FW Heat Genpar, LLC. Mr. Hebert may be deemed to beneficially own the shares held by FW Heat Genpar, LLC, as in his role as the sole member of the FW Heat Genpar, LLC, he has sole control over the voting and disposition of any shares held by FW Heat Investors, L.P. Mr. Hebert disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a-1(a)(2) promulgated under the Exchange Act) that he may have in FW Heat Investors, L.P.

## CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

The following is a summary of transactions since January 1, 2011 to which we have been a party in which the amount involved exceeded the lesser of \$120,000 or one percent of the average of our total assets at the end of the last two recent fiscal years and in which any of our executive officers, directors or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this prospectus entitled "Management—Non-Employee Director Compensation" and "Management — Executive Compensation."

Pursuant to our funding agreement with the University of Miami, the University has been issued shares of Heat Biologics I, Inc. representing 7.5% of the outstanding shares of Heat Biologics I, Inc.

In 2010, we issued convertible notes in the aggregate principal amount of \$926,000 to Brightline Ventures III, LLC, the managing member of which is Edward Smith, a member of our board of directors. In 2011, we issued additional convertible notes in the aggregate principal amount of \$1,347,709 to the same investor. In September 2011, all of the notes were converted into 1,101,769 shares of Series A Preferred Stock.

We paid Dr. Eckhard Podack, the Chairman of our Scientific and Advisory Board and a holder of in excess of 5% of our outstanding shares of common stock, consulting fees of \$18,750 and \$43,750 for the years ended December 31, 2012 and 2011, respectively.

We paid Sol Barer, a member of our Scientific and Clinical Advisory Board \$50,000 in consulting fees for the year ended December 31, 2011.

During the year ended December 31, 2012 and 2011, we paid \$30,910 and \$26,000, respectively, to Taffy Williams, a prior member of management, for consulting fees.

During the year ended December 31, 2010, Jeffrey Wolf advanced the Company \$12,500. Interest is calculated on the outstanding balance annually at 3.25%. As of December 31, 2012 and 2011, the outstanding balance was \$0 and \$12,500, respectively. At December 31, 2012 and 2011, accrued interest on this payable was \$0 and \$686, respectively.

The Company had a related party payable balance of \$0 and \$12,371 as of December 31, 2012 and 2011, respectively to Jeffrey Wolf.

In June 2012, we sold our 92.5% interest in Heat Biologics II, Inc. to a related party entity in exchange for \$9,250 in cash and a receivable of \$296,224 based upon an independent appraisal report issued April 2012. Interest accrues on the receivable at a rate of 6% per annum. At December 31, 2012, the Company had a related party receivable from this entity for \$9,571 related to invoices received by the Company pertaining to expenses of Heat II incurred subsequent to the sale of Heat II. This amount is also recorded in the Company's accounts payable as of December 31, 2012.

In March 2013, Dr. Belsky, Dr. Monahan and Mr. Wolf each purchased 2,622 shares of the Company's Series B-1 Preferred Stock at a per share price of \$2.67 in its private placement that consummated in March 2013.

## SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there was no public market in the United States for our securities and a significant public market for our securities may not develop or be sustained after this offering. As described below, approximately 3,583,654 shares of our common stock that will be outstanding upon consummation of this offering will not be available for sale immediately after this offering due to certain contractual and securities law restrictions on resale. Sales of substantial amounts of our common stock in the public market after these restrictions lapse could cause the prevailing market price to decline and limit our ability to raise equity capital in the future.

Upon completion of this offering, we will have outstanding an aggregate of 5,856,381 shares of common stock (6,197,290 shares if the underwriters exercise their over-allotment option in full). In addition, we have reserved:

- 53,159 shares for issuance in connection with warrants outstanding as of May 21, 2013;
- 662,543 shares for issuance in connection with options outstanding as of May 21, 2013;
- 84,314 shares reserved for future issuance in under our equity incentive plans as of May 21, 2012 of which 21,348 shares have been reserved for option grants to be issued upon consummation of our initial public offering; and

Of these shares, the 2,272,727 shares sold in this offering (2,613,636 shares if the underwriters exercise their over-allotment option in full) will be freely transferable without restriction or further registration under the Securities Act, except for any shares that are acquired by affiliates as that term is defined in Rule 144 under the Securities Act ("Rule 144"). The remaining 3,583,654 shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 or 701 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- the 2,272,727 shares sold in this offering (2,613,636 shares if the underwriters exercise their over-allotment option in full) will be eligible for resale immediately; and
- approximately 3,583,654 restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the reporting requirements under the Exchange Act for at least 90 days a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, would be entitled to sell those shares, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the availability of current public information about us.

An affiliate of ours who has beneficially owned restricted shares of our common stock for at least twelve months (or six months, provided that such sale occurs after we have been subject to the reporting requirements under the Exchange Act for at least 90 days) would be entitled to sell, within any three-month period, a number of shares that does not exceed the greater of (i) 1% of shares of our common stock then outstanding and (ii) the average weekly trading volume of our common stock on the NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

## Rule 701

Under Rule 701, common stock acquired upon the exercise of certain currently outstanding options or pursuant to other rights granted under our stock plans may be resold, to the extent not subject to lock-up agreements, (a) by persons other than affiliates, beginning 90 days after the effective date of this offering, and (b) by affiliates, subject to the manner-of-sale, volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the holding period requirement of Rule 144. The Rule 701 shares held by our executive officers, directors and substantially all of our stockholders are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of the contractual lock-up agreements. The underwriters may release all or any portion of the securities subject to lock-up agreements.

## Lock-Up Agreements

In connection with this offering, our directors and officers and all holders of our outstanding equity securities, on an as converted basis, agreed not to sell or otherwise dispose of any securities without the prior written consent of Aegis Capital Corp. for a period of 180 days after the date of this prospectus, subject to certain terms and conditions. See the section entitled "Underwriting" for more information regarding such restrictions.

## Registration Rights

After the closing of this offering, certain holders of our securities will be entitled to rights with respect to the registration of their shares under the Securities Act. At any time after the: (i) one year anniversary of their investment; (ii) 180 days after the closing of an initial public offering; (iii) the completion by us of a merger, consolidation, sale, transfer, lease or other conveyance of all or substantially all of the assets or any other similar business combination or transaction with another company listed on the New York Stock Exchange, the NYSE MKT, the NASDAQ National Market or the NASDAQ SmallCap Market; or (iv) the date upon which we become a reporting company under Section 12 or 15 of the Exchange Act other than in connection with our initial public offering, (1) the holders of Series B Preferred Stock have two demand registration rights upon request by holders of at least 50% of the then outstanding Registrable Securities (as defined below) attributable to or originally attributable to the Series B Preferred Stock, or a lesser percentage if the anticipated aggregate offering price of the Registrable Securities requested to be included in any such registration is at least \$5,000,000; and (2) the holders of Series 1 and Series A Preferred Stock have two demand registration rights upon written request by holders of at least 50% of the Registrable Securities not attributable or originally attributable to the Series B Preferred Stock. The holders of the Series 1, Series A and Series B Preferred Stock shall have unlimited piggyback registration rights and unlimited registrations on Form S-3 so long as the aggregate offering price to the public of Registrable Securities proposed to be included in such registration is not less than \$1,000,000. Registrable Securities is defined as the shares of common stock: (i) issued or issuable upon conversion of Series 1, Series A and Series B Preferred Stock; (ii) held or deemed held by the holders of the Series 1, Series A and Series B Preferred Stock pursuant to rights of first refusal or other purchase rights; (iii) issued in connection with the exercise of any warrants granted to the Series 1, Series A and Series B Holders; and (iv) issued or issuable as a dividend or other distribution on such shares of common stock. Registrable Securities do not include any securities: (i) sold by a person to the public either pursuant to a registration statement or Rule 144; (ii) sold in a private transaction in which the transferor's rights are not assigned or properly assigned; or (iii) that are eligible for sale without restriction under Rule 144. In addition, the shares underlying the warrant issued to Square 1 Bank are entitled to piggyback registration rights.

**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES  
TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion describes the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to the initial public offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences and does not address any tax consequences arising under any state, local or foreign tax laws, any income tax treaties, or any other U.S. federal tax laws, including U.S. federal estate and gift tax laws (except as specifically addressed herein with respect to U.S. federal estate taxes). This discussion is based on the Internal Revenue Code of 1986, as amended (“Code”), U.S. Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (“IRS”), all as in effect on the date of the initial public offering. These authorities may change, possibly retroactively, resulting in tax consequences different from those discussed below. No rulings have been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a different position regarding the tax consequences of a non-U.S. holder’s acquisition, ownership or disposition of our common stock or that any such position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as “capital assets” within the meaning of Code Section 1221 (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of the holder’s particular circumstances. It also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including, without limitation, U.S. expatriates, banks, financial institutions, insurance companies, regulated investment companies, real estate investment trusts, “controlled foreign corporations,” “passive foreign investment companies,” corporations that accumulate earnings to avoid U.S. federal income tax, brokers, dealers or traders in securities, commodities or currencies, partnerships or other pass-through entities (or investors in such entities), tax-exempt organizations, tax-qualified retirement plans, persons subject to the alternative minimum tax or the unearned income Medicare contribution tax, and persons holding our common stock as part of a straddle, hedge or other risk reduction strategy or as part of a conversion transaction or other integrated investment.

**WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY APPLICABLE INCOME TAX TREATIES, OR ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING ESTATE AND GIFT TAX LAWS).**

**Definition of Non-U.S. Holder**

As used in this discussion, a non-U.S. holder is any beneficial owner of our common stock who is not treated as a partnership for U.S. federal income tax purposes and is not:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a U.S. court is able to exercise primary supervision over its administration and one or more U.S. persons have authority to control all its substantial decisions or (ii) the trust was in existence on August 20, 1996, was treated as a U.S. person prior to that date and validly elected to continue to be so treated.

If any entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. Partnerships and their partners should consult their tax advisors as to the tax consequences to them of the acquisition, ownership and disposition of our common stock.



## Distributions on Our Common Stock

As described in the section entitled, “Dividend Policy,” we do not anticipate paying dividends on our common stock in the foreseeable future. If we make a distribution of cash or other property with respect to our common stock, the distribution generally will constitute a dividend for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s adjusted tax basis in its common stock, but not below zero. Any remaining excess will be treated as capital gain from the sale of property.

Dividends paid to a non-U.S. holder of our common stock that are not effectively connected to the holder’s conduct of a U.S. trade or business generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or a lower rate specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying the holder’s qualification for the reduced rate. A non-U.S. holder may be required to obtain a U.S. taxpayer identification number to claim treaty benefits. This certification must be provided to us or our paying agent prior to the payment of dividends and may be required to be updated periodically. Non-U.S. holders that do not timely provide us or our paying agent with the required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on the common stock are effectively connected with the holder’s U.S. trade or business and, if an income tax treaty applies, the non-U.S. holder maintains a “permanent establishment” in the United States to which the dividends are attributable, the non-U.S. holder will be exempt from U.S. federal withholding tax, if the appropriate certification is provided. To claim the exemption for effectively connected income, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or applicable successor form) prior to the payment of the dividends. Any dividends paid on our common stock that are effectively connected with a non-U.S. holder’s U.S. trade or business generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the holder were a resident of the United States, unless the holder is entitled to the benefits of a tax treaty that provides otherwise. A non-U.S. holder that is a foreign corporation also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of its effectively connected earnings and profits for the taxable year that are attributable to such dividends. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

## Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and foreign accounts, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a trade or business in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder’s holding period for our common stock and certain other requirements are met.

Unless an applicable tax treaty provides otherwise, gain described in the first bullet point above will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the holder were a resident of the United States. Non-U.S. holders that are foreign corporations also may be subject to a branch profits tax equal to 30% (or a lower rate specified by an applicable tax treaty) of its effectively connected earnings and profits for the taxable year that are attributable to such gain. Non-U.S. holders should consult any applicable tax treaties that may provide for different rules.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or a lower rate specified by an applicable income tax treaty), but may be offset by U.S. source capital losses.

With respect to the third bullet point above, we believe we currently are not and will not become a U.S. real property holding corporation. However, because the determination of whether we are a U.S. real property holding corporation generally depends on whether the fair market value of our U.S. real property interests equals or exceeds 50% of the sum of the fair market value of our other trade or business assets and our worldwide real property interests, there can be no assurance that we will not become a U.S. real property holding corporation in the future. In the event we do become a U.S. real property holding corporation, as long as our common stock is regularly traded on an established securities market, our common stock will constitute a U.S. real property interest only with respect to a non-U.S. holder that actually or constructively holds more than five percent of our common stock at some time during the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock. Any taxable gain generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

#### **Information Reporting and Backup Withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends on our common stock paid to the holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established.

Backup withholding, currently at a rate of 28%, generally will not apply to payments of dividends to a non-U.S. holder of our common stock provided the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status (typically, by providing a valid IRS Form W-8BEN or W-8ECI) or an exemption is otherwise established.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through a foreign office of a broker will not be subject to information reporting or backup withholding, except that information reporting (but generally not backup withholding) may apply to those payments if the broker does not have documentary evidence that the beneficial owner is a non-U.S. holder, an exemption is not otherwise established and the broker is:

- a U.S. person, as defined in the Code;
- a controlled foreign corporation for U.S. federal income tax purposes;
- a foreign person 50% or more of whose gross income is effectively connected with a U.S. trade or business for a specified three-year period; or
- a foreign partnership if at any time during its tax year (1) one or more of its partners are U.S. persons who hold in the aggregate more than 50% of the income or capital interest in the partnership or (2) it is engaged in the conduct of a U.S. trade or business.

Payment of the proceeds from a non-U.S. holder's disposition of our common stock made by or through the U.S. office of a broker generally will be subject to information reporting and backup withholding unless the non-U.S. holder certifies as to its non-U.S. status (such as by providing a valid IRS Form W-8BEN or W-8ECI) or otherwise establishes an exemption from information reporting and backup withholding.

Backup withholding is not an additional tax. Taxpayers may use amounts withheld as a credit against their U.S. federal income tax liability or may claim a refund if they timely provide certain information to the IRS.

#### **U.S. Federal Estate Tax**

Shares of common stock held (or deemed held) by an individual who is a non-U.S. holder at the time of his or her death will be included in such non-U.S. holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise, and thus may be subject to U.S. federal estate tax.

### **Additional Withholding Tax Relating to Foreign Accounts**

Legislation enacted in 2010 will generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to a foreign financial institution (whether holding stock for its own account or on behalf of its account holders/investors) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). The legislation will also generally impose a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid after December 31, 2012 to any other foreign entity unless such entity provides the withholding agent with a certification identifying the direct and indirect U.S. owners of the entity.

Recent administrative guidance provides, however, that such withholding would generally apply only to dividends paid on or after January 1, 2014, and to other “withholdable payments” (including payments of gross proceeds from a sale or other disposition of our common stock) made on or after January 1, 2017. Under certain circumstances, a holder might be eligible for refunds or credits of such taxes. Prospective investors are encouraged to consult with their own tax advisors regarding the possible impact of these rules on their investment in our common stock.

**WE RECOMMEND THAT PROSPECTIVE INVESTORS CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS, ANY APPLICABLE INCOME TAX TREATIES, OR ANY OTHER U.S. FEDERAL TAX LAWS (INCLUDING ESTATE AND GIFT TAX LAWS).**

## UNDERWRITING

Aegis Capital Corp. is acting as the sole book-running manager of the offering and as representative of the underwriters, or the Representative. We have entered into an underwriting agreement, dated \_\_\_\_\_, 2013, with the Representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
Aegis Capital Corp.	
Cantor Fitzgerald & Co.	
<b>Total</b>	<b><u>2,272,727</u></b>

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of 340,909 additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to the public will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

*Discount.* The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over-allotment Option	Total With Over-allotment Option
Public offering price	\$ _____	\$ _____	\$ _____
Underwriting discount (7%)	\$ _____	\$ _____	\$ _____
Non-accountable expense allowance (1%) <sup>(1)</sup>	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us	<u>\$ _____</u>	<u>\$ _____</u>	<u>\$ _____</u>

(1) The expense allowance of 1% is not payable with respect to the shares sold upon exercise of the underwriters' over-allotment option.

The underwriters propose to offer the shares to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of \$ \_\_\_\_\_ per share. If all of the shares offered by us are not sold at the public offering price per share, the underwriters may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We have paid an expense deposit of \$25,000 to the Representative, which will be applied against the accountable expenses that will be paid by us to the Representative in connection with this offering. The underwriting agreement provides that in the event the offering is terminated, the \$25,000 expense deposit paid to the Representative will be returned to us to the extent that offering expenses are not actually incurred by the Representative.

We have also agreed to pay the Representative's expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$2,500 per individual and \$15,000 in the aggregate; (b) all filing fees incurred in clearing this offering with FINRA (and the reasonable fees of FINRA counsel, but only up to \$15,000); (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (d) upon successfully completing this offering, \$21,775 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; and (e) upon successfully completing this offering, up to \$20,000 of the Representative's actual accountable road show expenses for the offering.

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately \$750,000.

*Discretionary Accounts.* The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

*Lock-Up Agreements.* Pursuant to certain "lock-up" agreements, we, our executive officers and directors, And all holders of our outstanding shares of common stock on a fully diluted basis (including shares underlying options, warrants and convertible securities) have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the Representative, for a period of 180 days from the date of effectiveness of the offering.

*Representative's Warrants.* We have agreed to issue to the Representative warrants to purchase up to a total of 113,636 shares of common stock (5% of the shares of common stock sold in this offering, but excluding the over-allotment option). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering, which period shall not extend further than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants are exercisable at a per share price equal to \$ \_\_\_\_\_ per share, or 125% of the public offering price per share in the offering. The warrants have been deemed compensation by FINRA and are therefore subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of effectiveness. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

*Right of First Refusal.* Subject to certain limited exceptions, until twelve (12) months after the date of effectiveness of the offering, the Representative has a right of first refusal to purchase for its account or to sell for our account, or any subsidiary or successor, any securities of our company or any such subsidiary or successor which we or any subsidiary or successor may seek to sell in public or private equity and public debt offerings during such twelve (12)-month period.

*NASDAQ Capital Market Listing.* Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol “HTBX.”

*Electronic Offer, Sale and Distribution of Shares.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The Representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Determination of the Initial Public Offering Price.* Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined through negotiations between us and the Representative of the underwriters. In addition to prevailing market conditions, the factors considered in determining the initial public offering price included the following:

- the information included in this prospectus and otherwise available to the Representative;
- the valuation multiples of publicly traded companies that the Representative believes to be comparable to us;
- our financial information;
- our prospects and the history and the prospectus of the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for our common stock may not develop. It is also possible that, after the offering, the shares will not trade in the public market at or above the initial public offering price.

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.
- Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could

be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the Representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive market making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

*Other Relationships.* Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

#### **Offer restrictions outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### ***Australia***

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

## **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

## **European Economic Area—Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

(a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

(c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

## **France**

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.



## ***Ireland***

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the “Prospectus Regulations”). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

## ***Israel***

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

## ***Italy***

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, “CONSOB” pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (“Decree No. 58”), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 (“Regulation no. 11971”) as amended (“Qualified Investors”); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

## ***Japan***

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder).

Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

#### ***Portugal***

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### ***Sweden***

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### ***Switzerland***

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

#### ***United Arab Emirates***

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates.

This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

*United Kingdom*

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Gracin & Marlow, LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Reed Smith LLP, New York, New York.

## EXPERTS

The consolidated financial statements of Heat Biologics, Inc. and Subsidiaries (a development stage company) as of December 31, 2012 and 2011 and for each of the two years in the period ended December 31, 2012 included in this prospectus and in the Registration Statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm appearing elsewhere herein and in the Registration Statement, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street, N.E., Room 1580, Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains an Internet web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov).

Upon the consummation of this offering, we will file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov).

Our website address is [www.heatbio.com](http://www.heatbio.com). The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

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(A Development Stage Company)

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**Report of Independent Registered Public Accounting Firm**

Board of Directors  
Heat Biologics, Inc. and Subsidiaries  
(A Development Stage Company)  
Chapel Hill, North Carolina

We have audited the accompanying consolidated balance sheets of Heat Biologics, Inc. and Subsidiaries (the "Company") (a development stage company) as of December 31, 2012 and 2011 and the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2012 and for the period from June 10, 2008 (inception) to December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Heat Biologics, Inc. and Subsidiaries at December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2012 and the period from June 10, 2008 (inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP  
Raleigh, North Carolina

April 8, 2013

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Consolidated Balance Sheets**

	<u>December 31,</u>		<u>March 31,</u>
	<u>2012</u>	<u>2011</u>	<u>2013</u>
			<u>(unaudited)</u>
<b>Assets</b>			
<b>Current Assets</b>			
Cash and cash equivalents	\$ 5,030	\$ 98,646	\$ 4,889,723
Related party receivable	9,571	—	—
Stock subscription receivable	—	—	35,000
Miscellaneous receivable	—	—	13,009
Prepaid expenses and other current assets	58,436	5,593	165,234
<b>Total Current Assets</b>	<u>73,037</u>	<u>104,239</u>	<u>5,102,966</u>
<b>Property and Equipment, net</b>	<u>10,782</u>	<u>11,589</u>	<u>9,968</u>
<b>Other Assets</b>			
Restricted cash	26,214	1,712	26,215
Debt issuance costs, net	28,229	55,007	27,500
Deposits	9,320	9,520	9,320
<b>Total Other Assets</b>	<u>63,763</u>	<u>66,239</u>	<u>63,035</u>
<b>Total Assets</b>	<u>\$ 147,582</u>	<u>\$ 182,067</u>	<u>\$ 5,175,969</u>
<b>Liabilities and Stockholders' (Deficit) Equity</b>			
<b>Current Liabilities</b>			
Accounts payable	\$ 505,471	\$ 352,125	\$ 861,615
Accrued expenses and other payables	129,208	25,901	170,315
Accrued interest	13,763	686	32,641
Related party payables	—	12,371	—
Liabilities related to discontinued operations	—	55,652	—
Notes payable - current portion	66,806	—	308,472
<b>Total Current Liabilities</b>	<u>715,248</u>	<u>446,735</u>	<u>1,373,043</u>
<b>Long Term Liabilities</b>			
Related party payable	—	12,500	—
Notes payable - less current portion	658,194	—	616,528
Convertible notes payable	197,099	—	465,106
Preferred stock warrants liability	92,150	56,930	77,300
<b>Total Liabilities</b>	<u>1,662,691</u>	<u>516,165</u>	<u>2,531,977</u>
<b>Commitments (Notes 9 and 13)</b>			
<b>Stockholders' (Deficit) Equity</b>			
Series 1 preferred stock, \$.0001 par value; 112,500 shares authorized, 112,500 shares issued and outstanding	11	11	11
Series A preferred stock, \$.0001 par value; 2,000,000 shares authorized, 1,863,128, 1,347,255, and 1,863,128 shares issued and outstanding at December 31, 2012 and 2011 and March 31, 2013 (unaudited)	186	134	186
Series B-1 preferred stock, \$.0001 par value; 4,100,000 shares authorized, 1,891,419 shares issued and outstanding at March 31, 2013 (unaudited)	—	—	189
Common stock, \$.0002 par value; 50,000,000 shares authorized, 2,144,542, 2,121,715 and 2,144,542 shares issued and 1,858,971, 1,827,449 and 1,861,145 shares outstanding at December 31, 2012 and 2011 and March 31, 2013 (unaudited)	405	400	405
Additional paid in capital	4,495,832	3,205,753	9,443,205
Deficit accumulated during the development stage	(5,935,282)	(3,515,082)	(6,699,138)
<b>Total Stockholders' (Deficit) Equity - Less Non-Controlling Interest</b>	<u>(1,438,848)</u>	<u>(308,784)</u>	<u>2,744,858</u>
<b>Non-Controlling Interest</b>	<u>(76,261)</u>	<u>(25,314)</u>	<u>(100,866)</u>
<b>Total Stockholders' (Deficit) Equity</b>	<u>(1,515,109)</u>	<u>(334,098)</u>	<u>2,643,992</u>
<b>Total Liabilities and Stockholders' (Deficit) Equity</b>	<u>\$ 147,582</u>	<u>\$ 182,067</u>	<u>\$ 5,175,969</u>

See accompanying notes to consolidated statements.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Consolidated Statements of Operations**

	Year Ended December 31,		Three Months Ended March 31,		June 10, 2008 (Inception) to March 31,
	2012	2011	2013 (As Restated)	2012 (unaudited)	2013 (As Restated) (unaudited)
<b>Revenue</b>					
Grant awards	\$ 3,110	\$ 187,787	\$ —	\$ —	\$ 585,589
<b>Operating Expenses</b>					
Research and development	902,938	1,246,587	440,289	170,765	\$ 3,797,771
Clinical and regulatory	253,189	255,210	62,057	46,807	489,900
General and administration	1,189,660	720,790	268,136	226,057	2,563,662
<b>Total Operating Expenses</b>	<u>2,345,787</u>	<u>2,222,587</u>	<u>770,482</u>	<u>443,629</u>	<u>6,851,333</u>
<b>Loss from Operations</b>	<u>(2,342,677)</u>	<u>(2,034,800)</u>	<u>(770,482)</u>	<u>(443,629)</u>	<u>(6,265,744)</u>
<b>Nonoperating Income (Expenses)</b>					
Interest income	2	517	1	—	688
Other (expense) income	(7,257)	(1,526)	10,362	(1,660)	1,579
Interest expense	(101,086)	(63,173)	(28,342)	(1,759)	(247,803)
<b>Total Nonoperating Expenses</b>	<u>(108,341)</u>	<u>(64,182)</u>	<u>(17,979)</u>	<u>(3,419)</u>	<u>(245,536)</u>
<b>Loss from Continuing Operations</b>	<u>(2,451,018)</u>	<u>(2,098,982)</u>	<u>(788,461)</u>	<u>(447,048)</u>	<u>(6,511,280)</u>
<b>Loss from Discontinued Operations</b>	<u>(20,129)</u>	<u>(14,160)</u>	<u>—</u>	<u>(1,100)</u>	<u>(288,724)</u>
<b>Net Loss Before Income Tax Expense</b>	<u>(2,471,147)</u>	<u>(2,113,142)</u>	<u>(788,461)</u>	<u>(448,148)</u>	<u>(6,800,004)</u>
<b>Income Tax Expense</b>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
<b>Net Loss</b>	<u>(2,471,147)</u>	<u>(2,113,142)</u>	<u>(788,461)</u>	<u>(448,148)</u>	<u>(6,800,004)</u>
Less: net loss - non-controlling interest	(50,947)	(8,258)	(24,605)	(6,464)	(100,866)
<b>Net Loss Attributable to Heat Biologics, Inc. and Subsidiaries</b>	<u>\$ (2,420,200)</u>	<u>\$ (2,104,884)</u>	<u>\$ (763,856)</u>	<u>\$ (441,684)</u>	<u>\$ (6,699,138)</u>
Less: beneficial conversion charge	—	—	(2,300,000)	—	(2,300,000)
<b>Net Loss Attributable to Common Shareholders</b>	<u>\$ (2,420,200)</u>	<u>\$ (2,104,884)</u>	<u>\$ (3,063,856)</u>	<u>\$ (441,684)</u>	<u>\$ (8,999,138)</u>
Basic and diluted loss per common share	<u>\$ (1.32)</u>	<u>\$ (1.15)</u>	<u>\$ (1.66)</u>	<u>\$ (0.24)</u>	
Basic and diluted weighted average common shares outstanding during the period	<u>1,831,769</u>	<u>1,824,927</u>	<u>1,859,929</u>	<u>1,830,597</u>	

See accompanying notes to consolidated statements.



**Heat Biologics, Inc. and Subsidiaries**  
(A Development Stage Company)

**Consolidated Statements of Stockholders' (Deficit) Equity**

	Preferred Stock Series 1 Amount	Preferred Stock Series A Amount	Preferred Stock Series B Amount	Common Stock Amount	Additional Paid In Capital	Deficit Accumulated During Development Stage	Non- Controlling Interest	Total Stockholders' (Deficit) Equity
<b>Common Stock Issued:</b>								
June 10, 2008, 1,395,559 shares	\$	—	\$	\$	321	\$	\$	\$ 321
July 11, 2008, 260,870 shares	—	—	—	60	—	—	—	60
July 11, 2008, 184,048 shares	—	—	—	42	—	—	—	42
Non-cash consideration for rent	—	—	—	—	4,104	—	—	4,104
Net loss	—	—	—	—	—	(281,971)	—	(281,971)
<b>Balance, December 31, 2008</b>	—	—	—	423	4,104	(281,971)	—	(277,444)
<b>Common Stock Issued:</b>								
January 1, 2009, 60,871 shares	—	—	—	14	—	—	—	14
April 20, 2009, 21,835 shares	—	—	—	5	—	—	—	5
April 29, 2009, 98,626 shares	—	—	—	23	—	—	—	23
<b>Common Stock Cancelled:</b>								
June 26, 2009, (282,672) shares	—	—	—	(65)	65	—	—	—
<b>Preferred Stock Issued:</b>								
November 3, 2009, 112,500 shares at \$2.22 per share	—	11	—	—	249,989	—	—	250,000
Non-cash consideration for rent	—	—	—	—	5,760	—	—	5,760
Stock based compensation	—	—	—	—	13,364	—	—	13,364
Net loss	—	—	—	—	—	(416,789)	(6,650)	(423,439)
<b>Balance, December 31, 2009</b>	—	11	—	400	273,282	(698,760)	(6,650)	(431,717)
Non-cash consideration for rent	—	—	—	—	5,760	—	—	5,760
Stock based compensation	—	—	—	—	30,791	—	—	30,791
Stock issuance costs	—	—	—	—	(7,584)	—	—	(7,584)
Net loss	—	—	—	—	—	(711,438)	(10,406)	(721,844)
<b>Balance, December 31, 2010</b>	—	11	—	400	302,249	(1,410,198)	(17,056)	(1,124,594)
<b>Notes Payable Converted to Preferred Stock:</b>								
September 30, 2011, 1,273,800 shares at \$2.10 per share	—	127	—	—	2,674,853	—	—	2,674,980
<b>Preferred Stock Issued:</b>								
December 20, 2011, 73,455 shares at \$2.10 per share	—	7	—	—	154,248	—	—	154,255
Preferred Series A Converted to Preferred Series 1, December 16, 2011, 112,500 shares at \$2.22 per share	11	(11)	—	—	—	—	—	—
Stock based compensation	—	—	—	—	91,984	—	—	91,984
Stock issuance costs	—	—	—	—	(17,581)	—	—	(17,581)
Net loss	—	—	—	—	—	(2,104,884)	(8,258)	(2,113,142)
<b>Balance, December 31, 2011</b>	\$ 11	\$ 134	\$ —	\$ 400	\$ 3,205,753	\$ (3,515,082)	\$ (25,314)	\$ (334,098)

See accompanying notes to consolidated statements.

**Heat Biologics, Inc. and Subsidiaries**  
(A Development Stage Company)

**Consolidated Statements of Stockholders' (Deficit) Equity (Continued)**

	Preferred Stock Series 1 Amount	Preferred Stock Series A Amount	Preferred Stock Series B Amount	Common Stock Amount	Additional Paid In Capital	Deficit Accumulated During Development Stage	Non- Controlling Interest	Total Stockholders' (Deficit) Equity
<b>Balance, December 31, 2011</b>	\$ 11	\$ 134	\$ —	\$ 400	\$ 3,205,753	\$ (3,515,082)	\$ (25,314)	\$ (334,098)
<b>Preferred Stock Issued:</b>								
March 7, 2012, 47,619 shares at \$2.10 per share	—	5	—	—	99,995	—	—	100,000
April 3, 2012, 39,683 shares at \$2.10 per share	—	4	—	—	83,330	—	—	83,334
April 27, 2012, 428,571 shares at \$2.10 per share	—	43	—	—	899,957	—	—	900,000
<b>Common Stock Issued:</b>								
December 27, 2012, 1,087 shares	—	—	—	—	825	—	—	825
December 31, 2012, 21,740 shares	—	—	—	5	10,495	—	—	10,500
Stock based compensation	—	—	—	—	217,896	—	—	217,896
Stock issuance costs	—	—	—	—	(22,419)	—	—	(22,419)
Net loss	—	—	—	—	—	(2,420,200)	(50,947)	(2,471,147)
<b>Balance, December 31, 2012</b>	<b>11</b>	<b>186</b>	<b>—</b>	<b>405</b>	<b>4,495,832</b>	<b>(5,935,282)</b>	<b>(76,261)</b>	<b>(1,515,109)</b>
<b>Preferred Stock Issued:</b>								
March 25, 2013, 1,891,419 shares at \$2.67 per share (unaudited)	—	—	189	—	5,049,901	—	—	5,050,090
Stock based compensation (unaudited)	—	—	—	—	26,793	—	—	26,793
Stock issuance costs (unaudited)	—	—	—	—	(129,321)	—	—	(129,321)
Net loss (unaudited)	—	—	—	—	—	(763,856)	(24,605)	(788,461)
<b>Balance, March 31, 2013 (unaudited)</b>	<b><u>11</u></b>	<b><u>186</u></b>	<b><u>189</u></b>	<b><u>405</u></b>	<b><u>9,443,205</u></b>	<b><u>(6,699,138)</u></b>	<b><u>(100,866)</u></b>	<b><u>2,643,992</u></b>

See accompanying notes to consolidated statements.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Consolidated Statements of Cash Flows**

	Year Ended December 31,		Three Months Ended March 31,		June 10, 2008 (Inception) to March 31,
	2012	2011	2013	2012	2013
			(unaudited)		(unaudited)
<b>Operating Activities</b>					
Net loss	\$ (2,471,147)	\$ (2,113,142)	\$ (788,461)	\$ (448,148)	\$ (6,800,004)
Adjustments to reconcile net loss to net cash used by operations:					
Depreciation	2,587	624	814	646	4,025
Amortization of debt issuance costs	58,458	26,168	729	—	99,242
Remeasurement of fair value of preferred stock warrants liability	3,540	1,040	(14,850)	—	(10,270)
Non-cash consideration for rent	—	—	—	—	15,624
Stock based compensation	217,896	91,984	26,793	16,828	380,828
Increase (decrease) in cash arising from changes in assets and liabilities:					
Grants receivable	—	223,295	—	—	—
Related party receivable	(9,571)	—	9,571	—	—
Stock subscription receivable	—	—	(35,000)	—	(35,000)
Other receivables	—	—	(13,009)	—	(13,009)
Prepaid expenses and other current assets	(52,843)	(1,898)	(106,798)	(1,169)	(165,234)
Restricted cash	(24,502)	(1,712)	(1)	1,100	(26,215)
Deposits	200	(9,520)	—	200	(9,320)
Accounts payable	85,323	74,495	356,144	6,232	861,615
Accrued expenses and other payables	103,307	22,776	41,107	(12,316)	170,315
Accrued interest	13,077	36,791	18,878	858	83,912
<b>Net Cash Used in Operating Activities</b>	<b>(2,073,675)</b>	<b>(1,649,099)</b>	<b>(504,083)</b>	<b>(435,769)</b>	<b>(5,443,491)</b>
<b>Cash Flows from Investing Activities</b>					
Purchase of property and equipment	(1,780)	(12,213)	—	(1,780)	(13,993)
Decrease in loan receivable from officer	—	6,138	—	—	—
<b>Net Cash Used in Investing Activities</b>	<b>(1,780)</b>	<b>(6,075)</b>	<b>—</b>	<b>(1,780)</b>	<b>(13,993)</b>
<b>Financing Activities</b>					
Related party payable	(12,500)	—	—	—	—
Borrowings on notes payable	1,147,099	—	200,000	225,000	1,150,000
Borrowings on line of credit	—	—	—	66,442	273,427
Payments on notes payable	(225,000)	—	—	—	(225,000)
Payments on line of credit	—	—	—	—	(273,427)
Issuance of convertible notes payable, net of issuance costs	—	1,447,709	268,007	—	3,049,643
Issuance of common stock	11,325	—	—	—	11,790
Issuance of series A preferred stock	1,083,334	154,255	—	99,389	1,487,589
Issuance of series B-1 preferred stock	—	—	5,050,090	—	5,050,090
Stock issuance costs	(22,419)	(17,581)	(129,321)	—	(176,905)
<b>Net Cash Provided by Financing Activities</b>	<b>1,981,839</b>	<b>1,584,383</b>	<b>5,388,776</b>	<b>390,831</b>	<b>10,347,207</b>
<b>Net (Decrease) Increase in Cash and Cash Equivalents</b>	<b>(93,616)</b>	<b>(70,791)</b>	<b>4,884,693</b>	<b>(46,718)</b>	<b>4,889,723</b>
<b>Cash and Cash Equivalents – Beginning of Period</b>	<b>98,646</b>	<b>169,437</b>	<b>5,030</b>	<b>98,646</b>	<b>—</b>
<b>Cash and Cash Equivalents – End of Period</b>	<b>\$ 5,030</b>	<b>\$ 98,646</b>	<b>\$ 4,889,723</b>	<b>\$ 51,928</b>	<b>\$ 4,889,723</b>

See accompanying notes to consolidated statements.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Consolidated Statements of Cash Flows (Continued)**

	Year Ended December 31,		Three Months Ended March 31,		June 10, 2008 (Inception) to March 31,
	2012	2011	2013	2012	2013 (unaudited)
<b>Supplemental Disclosure for Cash Flow Information</b>					
Interest paid	\$ 29,049	\$ —	\$ 5,593	\$ —	\$ 83,359
<b>Supplemental Schedule of Noncash Investing and Financing Activities</b>					
Notes payable converted to series A preferred stock	\$ —	\$ 2,674,980	\$ —	\$ —	\$ 2,674,980
Issuance of preferred stock warrants and debt issuance costs	\$ 31,680	\$ 55,890	\$ —	\$ —	\$ 119,250
Cancellation of common stock	\$ —	\$ —	\$ —	\$ —	\$ 65
Non-cash consideration for rent	\$ —	\$ —	\$ —	\$ —	\$ 15,624

See accompanying notes to consolidated statements.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**1. Organization**

Heat Biologics, Inc., (“Heat”), was incorporated in 2008 pursuant to the laws of the state of Delaware. Heat Biologics, Inc. is a development stage company focused on the development and commercialization of *ImPact* Therapy, a platform technology that offers a novel approach to treating cancer and other diseases by using live, modified cell lines to activate the immune system against specific defined targets. Heat is currently in Phase 2 clinical trials with its first drug for patients with advanced non-small cell lung cancer. During 2010 and part of 2011, Heat was based in Miami Beach, Florida. In July 2011, Heat moved all administrative operations to Chapel Hill, North Carolina.

Heat has owned 92.5% interests in two subsidiaries, Heat Biologics I, Inc. and Heat Biologics II, Inc. since their incorporation in the state of Delaware and commencement of operations on April 28, 2009. In April of 2012, the Board of Directors approved the sale of Heat’s entire 92.5% interest in Heat II. An independent appraisal report, issued on April 18, 2012, was concurrently approved by the Board as an accurate assessment of Heat II’s fair market value of \$0.0025 per share. On June 25, 2012 a stock purchase agreement was executed for the purchase of 3,700,000 shares of Heat II common stock by a related party. The operations of Heat II through June 25, 2012, including fiscal year 2012 and 2011, and inception to date, are presented in the accompanying consolidated statements of operations as a loss from discontinued operations and on the consolidated balance sheets as liabilities related to discontinued operations.

On May 30, 2012, Heat formed two-wholly owned subsidiaries, Heat Biologics III, Inc. (“Heat III”) and Heat Biologics IV, Inc. (“Heat IV”). Heat also formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012. As of March 31, 2013, there had been no activity within Heat III, Heat IV, and Heat GmbH other than their formations.

Heat’s product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of Heat’s strategy is to develop and commercialize some of its product candidates by continuing existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

**2. Summary of Significant Accounting Policies**

*Basis of Accounting*

Heat prepares its consolidated financial statements on the accrual basis of accounting in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Activities during the development stage include developing the business plan, raising capital, and developing the Company’s platform technology.

*Principles of Consolidation*

The 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 2011 and March 31, 2013 (unaudited), Heat held a 92.5% controlling interest in Heat I and accounts for its less than 100% interest in the consolidated financial statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interests as a component of stockholders’ deficit on its consolidated balance sheets and reports non-controlling interest net income (loss) under the heading “net income (loss) – non-controlling interest” in the 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 consolidated statements of operations as a loss from discontinued operations and on the consolidated balance sheets as liabilities related to discontinued operations.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

***Use of Estimates***

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

***Unaudited Interim Financial Information***

The accompanying consolidated balance sheets as of March 31, 2013, consolidated statements of operations, consolidated cash flows and consolidated stockholders' (deficit) equity for the three months ended March 31, 2012 and 2013 and the cumulative period from inception (June 10, 2008) to March 31, 2013, are unaudited. The interim unaudited consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2013 and the results of its operations and its cash flows for the three months ended March 31, 2012 and 2013 and the cumulative period from inception (June 10, 2008) to March 31, 2013. The financial data and other information disclosed in these notes related to the three months ended March 31, 2012 and 2013 and the cumulative period from inception (June 10, 2008) to March 31, 2013 are unaudited. The results for the three months ended March 31, 2013 are not necessarily indicative of results to be expected for the year ending December 31, 2013, any other interim periods, or any future year or period.

***Cash and Cash Equivalents and Restricted Cash***

The Company considers all cash and other highly liquid investments with initial maturities of three months or less from the date of purchase to be cash and cash equivalents. The Company had a restricted cash balance of \$26,214 and \$1,712 at December 31, 2012 and 2011, respectively, and \$26,215 at March 31, 2012 (unaudited). The United States Patent and Trade Office ("USPTO") requires the Company to maintain an account with a minimum of \$1,000 to be used to pay fees associated with new trademarks of the Company and one of the Company's lenders requires a minimum \$25,000 cash balance to be maintained with the lending bank.

***Concentration of Credit Risk***

At times, cash balances may exceed the Federal Deposit Insurance Corporation ("FDIC") insurable limits. The Company has never experienced any losses related to these balances. All of the Company's cash balances were fully insured at December 31, 2012 and 2011. As of March 31, 2013, any cash balance above \$250,000 is not fully insured. Uninsured cash balance at March 31, 2013 (unaudited) was \$4,639,723. The Company believes it is not exposed to significant credit risk on cash and cash equivalents.

***Debt Issuance Costs, net***

Debt issuance costs include the costs incurred to obtain financing, including the fair value of preferred stock warrants at the date of issuance, and are amortized using the straight-line method, which approximates the effective interest method, over the life of the related debt. Debt issuance costs are included in the accompanying consolidated balance sheets net of amortization.

***Property and Equipment***

Property and equipment are stated at cost and are capitalized if the cost exceeds \$500. Depreciation is calculated using the straight-line method and is based on estimated useful lives of 3 years for computer equipment and seven years for furniture and fixtures.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

***Preferred Stock Warrant Liability***

In December 2011 and August 2012, the Company entered into a promissory note with each of two lenders and issued preferred stock warrants to each lender as consideration. The Company accounts for these freestanding warrants to purchase the Company's Series A Preferred Stock as liabilities at fair value on the accompanying consolidated balance sheets. The warrants may only be settled in shares of Series A Preferred Stock. The warrants are subject to re-measurement at each balance sheet date, and the change in fair value, if any, is recognized as other income (expense). The Company will continue to adjust the liability for changes in fair value until the earlier of (i) exercise of the warrants, (ii) conversion of the warrants into warrants to purchase common stock upon an event such as the completion of an initial public offering or (iii) expiration of the warrants. Upon conversion, the preferred stock warrant liability will be reclassified into additional paid-in capital. The Monte Carlo simulation is a generally accepted statistical method used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices and minimizes standard error.

Significant assumptions used in the valuation of the warrants were as follows:

	March 31, 2013	December 31,	
	(Unaudited)	2012	2011
Exercise price	\$4.83	\$4.83	\$4.83
Risk-free interest rate	1.56% – 1.87%	1.78%	1.65% – 1.92%
Expected volatility	76.2 – 76.3%	75.6 – 76.3%	75.1 – 76.7%
Expected life (years)	10	10	10
Expected dividend yield	0%	0%	0%

***Beneficial Conversion Feature***

When the Company issues an equity security that is convertible into common stock at a discount from the fair value of the common stock at the date the equity security counterparty is legally committed to purchase such a security (Commitment Date), a beneficial conversion charge is measured and recorded on the Commitment Date for the difference between the fair value of the Company's common stock and the effective conversion price of the equity security. If the intrinsic value of the beneficial conversion feature is greater than the proceeds allocated to the equity security, the amount of the discount assigned to the beneficial conversion feature is limited to the amount of the proceeds allocated to the equity security.

The amount allocated to the beneficial conversion feature is presented as an immediate charge to earnings available to common shareholders for convertible preferred stock instruments that are convertible by the shareholders at any time. In connection with the Company's issuance of Series B-1 Preferred Stock, the Company recorded a beneficial conversion charge of \$2.3 million representing the difference between the effective conversion price of \$6.14 and the fair value of the Company's common stock as of the Commitment Date of \$8.81.

***Net Loss per Share***

Basic net loss per share is computed by dividing net income by the weighted average number of common shares outstanding during each year. Fully diluted net loss per share is computed using the weighted average number of common shares and dilutive securities outstanding during each year. Dilutive securities having an anti-dilutive effect on diluted loss per share are excluded from the calculation.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

***Fair Value of Financial Instruments***

The carrying amount of certain of the Company's financial instruments, including prepaid expenses and other current assets, other assets, deposits, accounts payable, accrued expenses and other payables, and related party payable approximate fair value due to their short maturities. The carrying value of the Company's 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.

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:

	<u>December 31,</u>		<u>March 31,</u>	
	<u>2012</u>	<u>2011</u>	<u>2013</u>	<u>2012</u>
			<b>(unaudited)</b>	
Fair value at beginning of period	\$ 56,930	\$ —	\$ 92,150	\$ 56,930
Issuances	31,680	55,890	—	—
Change in fair value at end of period	<u>3,540</u>	<u>1,040</u>	<u>(14,850)</u>	<u>—</u>
Fair value at end of period	<u>\$ 92,150</u>	<u>\$ 56,930</u>	<u>\$ 77,300</u>	<u>\$ 56,930</u>

***Marketing***

Marketing costs are expensed as incurred. Marketing expense totaled \$5,921 and \$18,380 for the years ended December 31, 2012 and 2011, respectively. Marketing expense totaled \$1,600 and \$4,200 for the three months ended March 31, 2013 and 2012 (unaudited), respectively.

***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.



**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

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 December 31, 2012 and 2011 and March 31, 2013 (unaudited), 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 December 31, 2012 and 2011 and March 31, 2013 (unaudited), the Company had no such accruals.

***Stock-Based Compensation***

The Company accounts for stock-based compensation arrangements with employees and non-employee directors using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The expected term for the years ended December 31, 2012 and 2011 the three month ended March 31, 2013 and 2012 represents the average time that options are expected to be outstanding based on the mid-point between the vesting date and the end of the contractual term of the award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. The measurement of nonemployee share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period over which services are received.

***Net loss attributable to non-controlling interests***

Net loss attributable to non-controlling interests is the result of the Company's consolidation of subsidiaries of which it does not own 100%. The Company's net loss attributable to non-controlling interests relates to the University's ownership in Heat I, and its ownership of in Heat II before the divestiture of Heat II.

***Revenue Recognition***

The Company recognizes government grants when there is reasonable assurance that they will comply with the conditions attached to the grants and that the grants will be received. The grants are recognized using an income approach and grant revenue is recognized as the related expenses are incurred.

***Research and Development***

Research and development costs are expensed as incurred. The Company has acquired exclusive licensing rights to intellectual property to further its research and development. These costs are expensed as incurred. The Company also incurs legal costs relating to the filing and application fees for patents which are owned by the universities with which the Company has license agreements. These costs are also expensed as research and development expense as incurred.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (“FASB”) amended the FASB Accounting Standards Codification (“ASC”) to converge the fair value measurement guidance in U.S. GAAP and International Financial Reporting Standards. Some of the amendments clarify the application of existing fair value measurement requirements, while other amendments change particular principles in fair value measurement guidance. In addition, the amendments require additional fair value disclosures. The amendments are effective for fiscal years beginning after December 15, 2011 and should be applied prospectively. These amendments impact the Company’s financial statement disclosures only and became effective in 2012. The amendments did not have a material impact on the Company’s consolidated financial statements.

In August 2012, the Financial Accounting Standards Board (“FASB”) issued ASU 2012-03, *Technical Amendments and Corrections* to SEC Sections to amend various SEC sections in the Accounting Standards Codification as a result of (1) the issuance of SEC Staff Accounting Bulletin No. 114; (2) the issuance of SEC Release No. 33-9250; and (3) corrections related to ASU 2010-22, *Technical Corrections to SEC Paragraphs*. The new guidance was effective upon issuance, and the adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

In October 2012, the FASB issued ASU 2012-04 – *Technical Corrections and Improvements*. The amendments in this Update cover a wide range of topics within the codification, as they incorporate multiple improvements provided through the codification’s feedback process. Amendments have been made to source literature, guidance clarification, reference corrections and relocations of guidance. Amendments that do not have transition guidance were effective upon issuance. Amendments subject to transition guidance will be effective for fiscal periods beginning after December 15, 2012. The Company adopted the guidance effective January 1, 2013 and the adoption of this guidance did not have an impact on the Company’s consolidated financial statements.

**3. Restatement**

The financial statements as of March 31, 2013 have been revised to correct an error in accounting for the Company’s Series B-1 Convertible Preferred Stock. The Series B-1 Convertible Preferred Stock issued on March 25, 2013 contains a beneficial conversion feature that was not previously recognized. In accordance with the applicable GAAP, the Company calculated and recognized a beneficial conversion feature on the grant date equal to the intrinsic value of the conversion feature. The following table represents the effects of the restated statements as of March 31, 2013.

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2013</b>	<b>2013</b>
	<b>(As Restated)</b>	
	<b>(Unaudited)</b>	
<b>Revenue</b>	\$ —	\$ —
<b>Operating Expenses</b>	<u>770,482</u>	<u>770,482</u>
<b>Loss from Operations</b>	<u>(770,482)</u>	<u>(770,482)</u>
<b>Nonoperating Expenses</b>	<u>(17,979)</u>	<u>(17,979)</u>
<b>Net Loss</b>	(788,461)	(788,461)
Less: net loss - non-controlling interest	<u>(24,605)</u>	<u>(24,605)</u>
<b>Net Loss Attributable to Heat Biologics, Inc. and Subsidiaries</b>	\$ (763,856)	\$ (763,856)
Less: beneficial conversion charge	<u>—</u>	<u>(2,300,000)</u>
<b>Net Loss Attributable to Common Shareholders</b>	<u>\$ (763,856)</u>	<u>\$ (3,063,856)</u>
Basic and diluted loss per common share	<u>\$ (0.41)</u>	<u>\$ (1.66)</u>
Basic and diluted weighted average common shares outstanding during the period	<u>1,859,929</u>	<u>1,859,929</u>

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

**4. Discontinued Operations**

In April of 2012, the Company's board approved a plan to sell its 92.5% interest in Heat II to a related party entity. On June 25, 2012, the Company sold all of its interest to the related party in exchange for \$9,250 in cash and a receivable from the related party of \$296,244. The receivable is due in full approximately seven years from the date of the transaction with interest accruing at a rate of 6% per annum. The Company performed a fair value analysis of the receivable from the related party and determined that due to the uncertainty surrounding the collectibility of the receivable, the fair value was \$0. The Company's estimate of the fair value of the receivable is based upon several factors including the long-term maturity of the receivable, an analysis of the related party's ability and willingness to pay the receivable given the current financial position, and that fact that Heat II is likely years away from generating product revenues.

The \$9,250 in cash was recorded as a reduction to the loss from discontinued operations in the consolidated statement of operations for the year ended December 31, 2012. The operations of Heat II through June 25, 2012, including fiscal years 2012 and 2011, and inception to date, are presented in the accompanying consolidated statements of operations as a loss from discontinued operations and on the consolidated balance sheets as liabilities related to discontinued operations.

**5. Property and Equipment**

Property and equipment consist of the following at:

	Year ended December 31,		Three months ended March 31,
	2012	2011	2013 (unaudited)
Computer equipment	\$ 3,213	\$ 3,213	\$ 3,213
Furniture and fixtures	10,780	9,000	10,780
Less: accumulated depreciation	<u>(3,211)</u>	<u>(624)</u>	<u>(4,025)</u>
	<u>\$ 10,782</u>	<u>\$ 11,589</u>	<u>\$ 9,968</u>

Depreciation expense for the years ended December 31, 2012 and 2011 was \$2,587 and \$624, respectively. Depreciation expense for the three months ended March 31, 2013 and 2012 (unaudited) was \$814 and \$646, respectively.

**6. Debt Issuance Costs**

In connection with the issuance of convertible notes payable, the Company incurred debt acquisition costs in the amount of \$39,172. The Company capitalized these costs and amortized them over the life of the note payable, using the straight-line method of amortization. The outstanding notes payable were all converted to preferred stock during the year-ended December 31, 2011 at which time the remaining debt issuance costs related to the issuance of these convertible notes payable were written-off.

In December 2011, the Company recorded \$55,890 of debt issuance costs related to the issuance of warrants to purchase Series A Preferred Stock to a lender. The warrants were issued in conjunction with a promissory note issued to the lender. In December 2011, the Company began amortizing the debt issuance costs over the three year term of the promissory note resulting in \$883 of interest expense for the year ended December 31, 2011. The note payable associated with the preferred stock warrants was paid in full and terminated during 2012. The remaining balance of \$55,007 was amortized and written off during 2012.

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In August 2012, the Company recorded \$31,680 of debt issuance costs related to the issuance of warrants to purchase Series A Preferred Stock to a lender. The warrants were issued in conjunction with a promissory note issued to the lender. At this time, the Company began amortizing the debt issuance costs over the four year term of the promissory note resulting in interest expense of \$3,451 the year ended December 31, 2012. Unaudited interest expense for the three month period ended March 31, 2013 was \$729 related to the amortization of these debt issuance costs.

Total amortization expense for the debt issuance costs was \$58,548 and \$26,168 during fiscal year 2012 and 2011, respectively. Unaudited amortization expense was \$729 for the three month period ended March 31, 2013. Accumulated amortization at December 31, 2012 and 2011 was \$3,451 and \$39,172, respectively. Unaudited accumulated amortization at March 31, 2013 and 2012 was \$4,180 related to the amortization of these debt issuance costs.

**7. Convertible Notes Payable**

On May 18, 2010, the Company issued a convertible note payable to an investor in the amount of \$250,000 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in November 2011; however, the note payable, along with accrued interest of \$10,273, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 123,939 shares of preferred stock issued and \$260,260 of additional paid-in capital.

On May 24, 2010, the Company issued a convertible note payable to a related party in the amount of \$350,000 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in November 2011; however, the note payable, along with accrued interest of \$14,210, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 173,433 shares of preferred stock issued and \$364,192 of additional paid-in capital.

On September 30, 2010, the Company issued a convertible note payable to a related party in the amount of \$576,000 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in March 2012; however, the note payable, along with the accrued interest of \$17,279, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 282,514 shares of preferred stock issued and \$593,252 of additional paid-in capital.

On May 9, 2011, the Company issued a convertible note payable to a related party in the amount of \$425,000 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in November 2012; however, the note payable, along with the accrued interest of \$5,029, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 204,776 shares of preferred stock issued and \$430,009 of additional paid-in capital.

On June 1, 2011, the Company issued a convertible note payable to a related party in the amount of \$100,000 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in December 2012; however, the note payable, along with accrued interest of \$993, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 48,092 shares of preferred stock issued and \$100,988 of additional paid-in capital.

On August 15, 2011, the Company issued a convertible note payable to a related party in the amount of \$922,709 with an interest rate of 3% per annum, accruing monthly. The note is convertible into the Company's Series A Preferred Stock at a price per share of \$2.10. The note was scheduled to mature in February 2013; however, the note payable, along with accrued interest of \$3,487, was converted to Series A Preferred Stock on September 30, 2011. The conversion resulted in 441,046 shares of preferred stock issued and \$926,152 of additional paid-in capital.

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On October 20, 2011, the Company entered into a convertible note agreement with a vendor for an amount up to \$950,000. The note accrues 12% simple interest per annum beginning on the day of the first advance. The note is convertible into common or Series A preferred stock at the latest valuation. The type of security converted will depend on whether common or Series A preferred stock is issued as part of a successful future equity raise of at least \$7.5 million at the qualified offering price. Unless earlier converted into equity, the note will be payable upon demand after the eighth anniversary of the execution date of the vendor agreement which occurs in October 2019. The agreement allows the vendor to treat unpaid invoices as advances of principal under the promissory note. As of December 31, 2012 and 2011, the Company had drawn \$197,099 and \$0, respectively, on this note agreement. As of March 31, 2013 (unaudited), the Company had drawn \$465,106 on this note agreement. The note matures on October 20, 2019 unless the agreement is terminated earlier or the note is converted to Series A preferred stock or common stock.

Accrued interest on outstanding debt obligations was \$13,763 and \$686 at December 31, 2012 and 2011, respectively. Unaudited accrued interest at March 31, 2013 was \$32,641.

**8. Notes Payable**

On December 14, 2011, the Company entered into a loan agreement with the North Carolina Biotechnology Center (the "Center") for an amount up to \$250,000 to be used by the Company to develop certain of its proprietary technology and processes as defined by the loan agreement during a one year period ended December 14, 2012. The principal of the loan, plus accrued interest, is due in full on December 14, 2014, with annual installments of 5% of the outstanding balance due on December 14, 2012 and 2013. The loan agreement accrues interest at 4.25% per annum beginning on the day of the first advance. As of December 31, 2011, the outstanding balance was \$0 and no draw downs occurred during fiscal year 2011. During the year ended December 31, 2012, the Company drew down \$225,000 of the loan and then repaid the principal balance, including accrued interest, in full in August 2012. The loan agreement was canceled upon the repayment.

In conjunction with this loan agreement, the Company issued warrants to purchase 29,762 shares of Series A Preferred Stock with an exercise price of \$4.83 per share and an expiration date of December 13, 2021. Per the terms of the warrant agreement, the exercise price of \$4.83 per share is subject to adjustment if at any time subsequent to the date of the warrant agreement, Preferred Series A shares are issued at a price less than \$4.83 per share. The warrants were recorded at fair value as a liability on the Company's consolidated balance sheet on the date of issuance and are revalued as of each balance sheet date. (See Note 10 Preferred Stock Warrants Liability).

On August 7, 2012, the Company and Heat I entered into a loan and security agreement ("the Loan and Security Agreement") with a bank. The terms of the agreement provide for a \$1,000,000 term loan ("Tranche A") to be available to the Company and Heat I as of the date of the Loan and Security Agreement. The Tranche A term loan may be increased to \$2,775,000 upon the Company receiving grant funding totaling at least \$16,000,000. The Tranche A term loan accrues interest monthly at an interest rate of 3% plus Prime or 6% per annum, whichever is greater. The Tranche A term loan principal balance, along with any accrued interest, is to be paid in thirty-six equal monthly installments beginning September 7, 2013 and ending August 7, 2016. As of December 31, 2012, the Company's outstanding principal balance on the Tranche A term loan was \$500,000. As of March 31, 2013 (unaudited), the outstanding principal balance on the Tranche A term loan was \$500,000.

The Loan and Security Agreement provides for another term loan of \$1,000,000 ("Tranche B") upon the receipt of at least \$5,000,000 from the sale or issuance of the Company's equity securities to investors on or before December 15, 2012 ("Tranche B Equity Trigger Event"). The Tranche B term loan accrues interest monthly at an interest rate of 3% plus Prime or 6% per annum, whichever is greater. The Tranche B term loan principal balance, along with any accrued interest, is to be paid in equal monthly installments beginning on the 7th day of the month immediately following the 12 month period after the Tranche B Equity Trigger Event and ending August 7, 2016. As of March 31, 2013 (unaudited), the Company has not drawn on the Tranche B term loan.

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Additionally, the Loan and Security Agreement provides for a term loan in an aggregate principal amount not to exceed \$225,000 ("Term Loan B"). Payments of 5% of the outstanding principal balance, plus accrued interest are each due on August 2013 and 2014, with the remaining principal balance, plus all accrued interest, due December 14, 2014. The term loan accrues interest monthly at 4.25% per annum. Proceeds from the \$225,000 Term Loan B were used to pay in full the principal balance of the loan with the Center as noted above. As of December 31, 2012, the Company's outstanding principal balance on the Term Loan B was \$225,000. As of March 31, 2013, the unaudited outstanding principal balance on the Term Loan B was \$225,000. At December 31, 2012, the Company was not in compliance with certain financial covenants related to this debt agreement. On March 31, 2013, the Company achieved the Equity Milestone covenant requirement which required the Company to obtain \$4,500,000 in equity financing by March 31, 2013. As of March 31, 2013 (unaudited), the Company was in compliance with its financial covenants related to this debt agreement.

On January 10, 2013, the Company signed a Second Amendment to its Loan and Security Agreement which granted an extension of credit in the form of a Non-Formula Revolving Line ("the Non-Formula Line") for an amount up to \$200,000. This increase in credit was through a limited guaranty by an investor who secured the additional obligation by maintaining as collateral a money market account of a minimum of \$200,000 with the bank. This guarantee was only for the amounts arising from the Line. It was the intention of both the investor and the Company that the Line was to be repaid within a reasonable time period after the successful raise of capital but no later than January 9, 2014, the maturity date of the Line. The payoff of the Line would release the investor of its obligation to the bank. The outstanding balance on the Non-Formula Line was \$200,000 as of March 31, 2013 (unaudited).

In conjunction with the Loan and Security Agreement, the Company issued the bank warrants to purchase 17,500 shares of Heat's Series A Preferred Stock. The warrants were issued on August 7, 2012 with an initial exercise price of \$4.83 per share and expire on August 7, 2022. The warrants were recorded at fair value as a liability on the Company's consolidated balance sheet on the date of issuance and are revalued as of each balance sheet date. (See Note 10 Preferred Stock Warrants Liability).

As of March 31, 2013 (unaudited), future payments under the Company's notes payable agreements are:

2013	\$ 308,472
2014	380,417
2015	166,667
2016	69,444
<b>Total</b>	<b><u>\$ 925,000</u></b>

#### **9. License Agreements**

On July 11, 2008, Heat entered into two agreements with a research university (the "University") to license, from the University, certain technology and processes in various stages of patent pursuit on an exclusive basis for use in its research and development and commercial activities ("License Agreement 03-31, 05-39" and "License Agreement 97-14", or collectively "License Agreements"). Heat has the right to grant sublicenses under the License Agreements.

Heat is also responsible for all patent costs, past and future, associated with the preparation, filing, prosecution, issuance, and maintenance of United States patent applications. Heat is also required to make minimum royalty payments to the University under the terms of the License Agreements.

In connection with the License Agreements, Heat agreed to issue to the University 10% of all issued and outstanding common stock in each class and series on a fully-diluted basis together with rights to participate in future stock offerings.

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In April 2009, Heat and the University agreed to amend the original License Agreements of July 11, 2008 to extend the terms of payments. For the additional consideration of \$12,500 and additional stock of 2.5% of fully-dilutable shares issued and outstanding for each License Agreement, a revised extension date of August 11, 2009 was granted for all past due license fees and patent costs. Furthermore, the 10% original stock holdings were given assurance of anti-dilution protection until a "Qualified Investment" pursuant to this agreement. This anti-dilution protection has been extinguished with the subsequent agreement described below.

On June 26, 2009, Heat assigned all rights and obligations of License Agreement 03-31, 05-39 and License Agreement 97-14 to its subsidiaries, Heat II and Heat I, respectively. All previous stock ownership and rights of the University to participate in future stock offerings by Heat were mutually terminated. Heat I and Heat II agreed to issue the University 5% of each subsidiary's issued and outstanding common stock in each class and series on a fully-diluted basis, together with fully-dilutable common shares equal to 2.5% of the total number of shares in each class and series issued outstanding. As a result, the University owns 7.5% of Heat I and Heat II's issued and outstanding common stock. For each agreement, the Company agreed to make minimum royalty payments of \$10,000 for three years beginning 2010 due on the anniversary date of the agreements. Beginning in 2013, and thereafter for the life of the agreements, the minimum royalty payments shall be \$20,000 due on the same date. A milestone payment is due to the University from the Company no later than May 2017 of \$250,000 for License Agreement 97-14.

In August 2009, Heat II and the University entered into a second amendment ("Amendment 2") to License Agreement 03-31, 05-39 to extend the foregoing payment due dates for all past due license fees and patent costs.

In August 2009, Heat I and the University entered into a second amendment ("Amendment 2") to License Agreement 97-14 to extend the foregoing payment due dates for all past due license fees and patent costs.

In February 2010, Heat II and the University entered into a third amendment ("Amendment 4") to License Agreement 03-31, 05-39 to grant back to the University a certain non-exclusive license. In all other respects, the original agreement remained the same.

On August 30, 2010, Heat entered into an option agreement with another research university ("University II") to acquire the right to negotiate an exclusive license for certain materials which includes cancer bladder cells and all unmodified derivatives of these cells. An option fee of \$2,000 was paid on September 8, 2010 to grant a period of nine months for this consideration. In July 2011, the Company exercised the option to acquire the license for \$10,000. Heat paid an option fee of \$2,000, a license issue fee of \$10,000 and is obligated to pay an annual maintenance fee of \$10,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to \$50,000. In addition, the Company is obligated to make milestone payments of \$25,000, \$50,000 and \$75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial and \$250,000 upon the first commercial sale of a licensed product and \$350,000 upon annual net sales of \$250,000,000 or more. To date, the Company has paid \$22,000 to University II with respect to such license. The license agreements provide that the University II has the right to terminate the license should Heat cease to carry on its business, fail to make a required payment or otherwise materially breach or default in its obligations under the license agreement following the giving of notice and an opportunity to cure any such breach. The license agreement provides that if the Company does not achieve the following milestones within the required period, University II has the right to terminate the license agreement: completion of a Phase 1 clinical trial on or before January 1, 2015, a Phase 2 clinical trial on or before January 1, 2017, a Phase 3 clinical trial on or before January 1, 2019 and the first commercial sale of a product that includes the materials supplied by University II on or before January 1, 2020.

In October 2010, Heat II and the University entered into a fourth amendment ("Amendment 5") to License Agreement 03-31, 05-39 to grant to the licensor a non-exclusive license right for certain technology as research reagents and research tools.

On December 12, 2010, Heat II entered into a similar license agreement ("I-176") with the University for one component of complimentary technology to the July 11, 2008 agreement. Heat II agreed to pay the University a license fee of \$50,000 and a reimbursement of \$15,797 for past patent fees. Heat II also agreed to make a minimum royalty payment of \$10,000 during 2012.

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On February 18, 2011, Heat I entered into a license agreement (“SS114A”) with the University to obtain additional technology related to License Agreement 97-14. Heat I agreed to reimburse the University for all past patent costs of \$37,381. As partial consideration for the license, Heat II agreed to grant back certain exclusive rights to the University.

On February 18, 2011, Heat I entered into a license agreement (“143”) with the University to obtain additional technology related to License Agreement 97-14. In consideration for the license, Heat I agreed to pay the University a fee of \$50,000 and reimburse them for past patent costs of \$14,158.

On February 18, 2011, Heat I entered into a license agreement (“J110”) with the University to obtain additional technology related to License Agreement 97-14. In consideration for the license, Heat I agreed to pay the University a fee of \$10,000 and reimburse them for past patent costs of \$1,055.

On February 18, 2011, Heat I entered into a license agreement (“D-107”) with the University to obtain additional technology related to License Agreement 97-14.

On April 12, 2011, Heat entered into a non-exclusive evaluation and biological material license agreement with a not-for-profit corporation for evaluation and production of vaccines. In consideration for the evaluation and commercial use license, the license agreement provides for an evaluation term of twelve months subject to two additional renewals, and a non-exclusive commercial use license upon termination of the evaluation period to utilize the products the Company obtains in the evaluation to develop, make, use and sell licensed products. The license agreement has a term of forty years. Heat paid an evaluation fee and 2 renewal evaluation fees totaling \$15,000, and is obligated to pay a \$50,000 fee upon initiation of the commercial license and a less than 1% royalty based on sales of licensed products. In addition, Heat is obligated to make milestone payments of \$15,000, \$30,000 and \$60,000 upon initiation of a Phase I, Phase II, and Phase III trial, respectively; and \$200,000 upon receipt of marketing authorization. To date, the Company has paid \$15,000 to the not-for-profit corporation with respect to such license.

At December 31, 2011, Heat owed the University approximately \$160,000 in unpaid license fees. At December 19, 2012, Heat owed the University approximately \$102,784 in unpaid license fees. Heat entered into a payment agreement on December 19, 2012 to extend the payment due of Heat I obligations until the earlier of the closing of a Series B financing round or June 1, 2013. As consideration for the extension of payment Heat I shall make an additional payment to the University equal to 18% annual interest of the outstanding balance on or before the due date or at the University’s option convert into shares of preferred stock according to the terms stipulated in the agreement.

Future minimum royalty payments that are required to be paid with the passage of time through December 31, 2022 are as follows:

<u>Year ended December 31,</u>	
2013	\$ 30,000
2014	30,000
2015	30,000
2016	30,000
2017	280,000
Thereafter through 2022	<u>150,000</u>
Total	<u>\$ 550,000</u>

These payments do not include payments that are contingent upon the Company meeting certain criteria or milestones or certain events occurring.



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**10. Preferred Stock Warrants Liability**

The summary of warrant activity for the years ended December 31, 2012 and 2011 and three months ended March 31, 2013 is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2011	—	\$ —	—	—
Granted	29,762	4.83	9.9	\$ 1.88
Exercised	—	—	—	—
Expired/cancelled	—	—	—	—
Outstanding at December 31, 2011	29,762	\$ 4.83	9.9	\$ 1.91
Granted	17,500	\$ 4.83	9.9	\$ 1.81
Exercised	—	—	—	—
Expired/cancelled	—	—	—	—
Outstanding at December 31, 2012	47,262	\$ 4.83	9.4	\$ 1.78
Granted, (unaudited)	—	—	—	—
Exercised, (unaudited)	—	—	—	—
Expired/cancelled, (unaudited)	—	—	—	—
Outstanding at March 31, 2013, (unaudited)	<u>47,262</u>	<u>\$ 4.83</u>	<u>8.9</u>	<u>\$ 1.64</u>

The aggregate intrinsic value of the preferred stock warrants in the table above is \$0.00 at December 31, 2012, December 31, 2011, and March 31, 2013 (unaudited). The aggregate intrinsic value is before applicable income taxes and is calculated based on the difference between the exercise price of the warrants and the estimated fair market value of the Company's Series A Preferred Stock as of the respective dates.

**11. Stockholders' (Deficit) Equity**

Authorized Capital

Heat has authorized 2,112,500 shares of preferred stock (par value \$0.0001) as of December 31, 2012 and 2011. Of the 2,112,500 preferred stock shares authorized, 2,000,000 are designated as Series A and 112,500 as Series 1. Of the Series A Preferred Stock, 1,863,128 and 112,500 and 1,347,255 and 112,500 are issued and outstanding as of December 31, 2012 and 2011, respectively and 1,863,128 and 112,500 are issued and outstanding as of March 31, 2013 (unaudited). In April 2011, an amended and restated Certificate of Incorporation was filed, and Heat reclassified and substituted 112,500 Series A preferred shares for Series 1 preferred shares. All of the original rights and preferences of the Series A were transferred to the Series 1 preferred stock. Of the Series 1 preferred stock, 112,500 are issued and outstanding as of December 31, 2012 and 2011 and March 31, 2013 (unaudited). In March 2013, an amended and restated Certificate of Incorporation was filed which authorized 8,212,500 shares of preferred stock which is designated as 2,000,000 shares of Series A, 112,500 shares of Series 1, 4,100,000 shares of Series B-1, and 2,000,000 shares of Series B-2. As of March 31, 2013 (unaudited), the Company had 1,891,419 and 0 shares of Series B-1 and Series B-2 Preferred Stock issued and outstanding, respectively. As of March 31, 2013, the Company recorded a receivable of \$35,000, which represents the amount owed by a shareholder with respect to the purchase of the Series B-1 Preferred Stock. This amount has subsequently been paid to the Company by the shareholder.

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Heat authorized 50,000,000 shares of common stock (par value \$0.0002) as of December 31, 2012 and 2011 and March 31, 2013 (unaudited). Of the 50,000,000 common stock shares, 2,144,542 and 2,121,715 were issued and 1,858,971 and 1,827,449 were outstanding as December 31, 2012 and 2011, respectively. Of the 50,000,000 common stock shares, 2,144,542 and 1,861,145 are issued and outstanding, respectively, as of March 31, 2013 (unaudited).

Preferred Stock

*Series 1, Series A, Series B-1, and Series B-2*

*Automatic Conversion*

Each share of Preferred Stock automatically converts to common stock upon the earlier to occur of (i) on the date of consummation of a sale of common stock in a firm commitment underwritten public offering resulting in aggregate net cash proceeds to the Company (after deducting applicable underwriting discounts and commissions) of at least \$15 million net proceeds; (ii) with respect to the Series A Preferred Stock, if 2/3 of the Series A Preferred Stock holders (including one of the larger investors so long as they hold 40% of the Series A Preferred Stock) vote in favor of a conversion then the Series A will automatically convert to common stock; (iii) with respect to the Series 1 Preferred Stock, if 2/3 of the Series 1 Preferred Stock holders vote in favor of a conversion then the Series 1 will automatically convert to common stock; and (iv) with respect to the Series B Preferred Stock if 2/3 of the Series B Preferred Stock holders vote in favor of a conversion then the Series B will automatically convert to common stock.

*Optional Conversion*

The preferred stock is convertible into common stock at the option of the holder at any time. The conversion ratio for each share of the Series 1 Preferred Stock and the Series A Preferred Stock is its Original Issue Price (\$2.35 and \$2.10 for each share of the Series 1 Preferred Stock and Series A Preferred Stock, respectively) divided by its Conversion Price, as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like, which Conversion Price initially was the Original Issue Price. The conversion ratio for each share of the Series B-1 Preferred Stock and the Series B-2 Preferred Stock is its Original Issue Price (\$2.67 and \$5.00 for each share of the Series B-1 Preferred Stock and Series B-2 Preferred Stock, respectively) plus accrued but unpaid dividends thereon divided by its conversion price, as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like, which conversion price initially was the Original Issue Price. As a result of the 1-for-2.3 reverse stock split, the conversion ratio for the Preferred Stock was 0.4348.

In the event the Company at any time or from time to time after the Initial Series B Issuance Date shall issue additional shares of common stock without consideration or for consideration per share less than the Series 1 Conversion Price, Series A Conversion Price, Series B-1 Conversion Price, or Series B-2 Conversion Price, in effect on the date of and immediately prior to such issue, then the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, Series B-2 Conversion Price, shall be reduced, to a price determined by multiplying the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price in effect by a fraction, (A) the numerator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of shares of common stock which the aggregate consideration received by the Company for the total number of Additional Shares of Common Stock so issued would purchase at the Series 1 Conversion Price, Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price, as in effect immediately prior to such issuance, and (B) the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of such Additional Shares of common stock so issued. To date no such adjustment has occurred.

The preferred stock was determined to have characteristics more akin to equity than debt. Particularly, the preferred stock has no mandatory redemption provision nor is it redeemable at the option of the holder. As a result, the conversion option was determined to be clearly and closely related to the preferred stock and therefore does not need to be bifurcated and classified as a liability.

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*Dividends*

The Series B Preferred Stock has a priority with respect to dividend distributions and distributions upon liquidation. The Series B Preferred Stock receive dividends when and as and if declared by the Board at a rate of 5% of their original issue price of such shares which is \$6.14 per share for the Series B-1 Preferred Stock and \$11.50 per share for the Series B-2 Preferred Stock. If the Company declares or pays a dividend upon the common stock, they must also pay to the holders of the Series A, 1 and B Preferred Stock the dividends that would have been declared with respect to common stock issuable upon conversion of the Series A, 1 and B Preferred Stock; provided, however that the Company cannot declare or pay a dividend unless and until all accrued dividends on the Series B Preferred Stock have been paid.

*Liquidation*

In the event of a liquidation, the holders of the Series B-1 and B-2 Preferred Stock are entitled to receive before any payment to any other Preferred Stockholder or common stock holder and pari passu with the holders of the Series 1 Preferred Stock an amount per share equal to the greater of \$6.14 for the Series B-1 Preferred Stock and \$11.50 for the Series B-2 Preferred Stock plus any dividends accrued and unpaid whether or not declared. After payment in full of the Series B Preferred Stockholders the holders of the Series A Preferred Stock are entitled to receive before any payment to the common stock holder and pari passu with the holders of the Series 1 Preferred Stock an amount per share equal to \$4.83 plus any dividends declared but unpaid. In the event of a liquidation, the holders of the Series 1 Preferred Stock are entitled to receive before any payment to the common stock holder and pari passu with any distribution to the Series A Preferred Stock an amount per share equal to \$5.41 plus any dividends declared but unpaid. After the payment in full of the amounts set forth above, the Company's assets will be distributed ratably to all holders of common stock and Series B Preferred Stock on an as converted basis except that the Series B Preferred Stockholders shall not continue to share in such distribution after each has received 3 times its Original Issue Price.

*Voting Rights*

Each holder of Preferred Stock is entitled to vote on all matters stockholders are entitled to vote and to cast the number of votes as shall equal the whole number of shares of common stock into which their shares of Preferred Stock are convertible.

Non-cash Consideration for Rent

Non-cash consideration for rent represents office space and other utilities provided by an unrelated entity on behalf of the Company during the years ended December 31, 2008 through December 31, 2010. No cash was transferred for the utilization of the space. The fair market value of the non-cash consideration was calculated using market rental rates and the square footage of office space provided.

Equity Compensation Plan

**2009 Stock Incentive Plan**

In 2009, the Company adopted the 2009 Stock Option Plan of Heat Biologics, Inc. (the "2009 Plan"), under which stock options to acquire 217,391 common shares could be granted to key employees, directors, and independent contractors. Under the 2009 Plan, both incentive and non-qualified stock options could be granted under terms and conditions established by the Board of Directors. The exercise price for incentive stock options was the fair market value of the related common stock on the date the stock option was granted. Stock options granted under the 2009 Plan generally have terms of 10 years and have various vesting schedules.

The Company amended the 2009 Stock Option Plan and all related addendum agreements in April 2011. This second amendment increased the number of shares available for issuance from 217,391 to 652,174. As of December 31, 2012 and 2011, there were 590,047 and 471,905 stock options outstanding under the 2009 Plan, respectively. As of March 31, 2013 (unaudited), there were 590,047 stock options outstanding under the 2009 Plan.

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The following table summarizes the components of the Company's stock-based compensation included in net loss:

	Year ended December 31,		Three months ended March 31,	
	2012	2011	2013	2012 (unaudited)
Employee stock options	\$ 60,956	\$ 51,686	\$ 7,777	\$ 6,106
Non-employee stock options	128,157	11,324	13,216	9,322
Restricted stock awards	28,783	16,540	5,800	1,400
	<u>\$ 217,896</u>	<u>\$ 79,550</u>	<u>\$ 26,793</u>	<u>\$ 16,828</u>

**Stock Options**

The fair market value of the stock options at the date of grant and re-measurement date was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Year ended December 31,		Three months ended March 31, (unaudited)	
	2012	2011	2013	2012
Risk-free interest rate	0.72 – 0.97%	0.71 – 1.16%	0.76 – 0.88%	0.91 – 1.40%
Expected volatility	80-90%	70%	90%	70%
Expected life (years)	5.0 – 6.25	3.5 – 6.25	4.7 – 5.75	3.5 – 6.25
Expected dividend yield	0%	0%	0%	0%

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.

The Company recognized stock compensation expense of \$217,896 and \$79,550 for the years ended December 31, 2012 and 2011, respectively for the Company's stock option awards. The Company recognized stock compensation expense of \$26,793 and \$16,828 for the three month periods ended March 31, 2013 and 2012 (unaudited), respectively, for the Company's stock option awards.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

The following tables summarize the stock option activity as of December 31, 2012 and 2011 and March 31, 2013 (unaudited):

	<u>Shares</u>	<u>Weighted Average Exercise Price</u>
Options at January 1, 2011	143,580	\$ 0.58
Granted	334,031	0.67
Exercised	—	—
Expired/cancelled	(5,706)	0.64
Options at December 31, 2011	471,905	\$ 0.64
Granted	178,742	0.76
Exercised	(22,827)	0.51
Expired/cancelled	(37,773)	0.02
Options at December 31, 2012	590,047	\$ 0.71
Granted, (unaudited)	—	—
Exercised, (unaudited)	—	—
Expired/cancelled, (unaudited)	—	—
Options at March 31, 2013, (unaudited)	<u>590,047</u>	<u>\$ 0.71</u>

The weighted average grant date fair value of stock options granted during the years ended December 31, 2012 and 2011 was \$1.31 and \$0.37, respectively. There were no stock options granted during the three months ended March 31, 2013 (unaudited).

The following table summarizes information about stock options outstanding at December 31, 2012:

<u>Options Outstanding</u>			<u>Options Exercisable</u>		
Balance as of December 31, 2012	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of December 31, 2012	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
590,047	8.34	\$0.74	431,951	8.70	\$0.64

As of December 31, 2012, the unrecognized stock-based compensation expense related to unvested stock options was approximately \$153,126, which is expected to be recognized over a weighted average period of approximately 34 months.

The aggregate intrinsic value of stock options outstanding and exercisable at December 31, 2012 was approximately \$890,000 and \$690,000, respectively. This amount is before applicable income taxes and represents the market price of the Company's common stock at December 31, 2012 less the grant price, multiplied by the number of stock options that had a grant price that is less than the market price. This amount represents the amount that would have been received by the optionees had these stock options been exercised on that date. During the year ended December 31, 2012, the aggregate intrinsic value of stock options exercised was \$39,600.

**Heat Biologics, Inc. and Subsidiaries**  
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The following table summarizes information about stock options outstanding at March 31, 2013 (unaudited):

Options Outstanding			Options Exercisable		
Balance as of March 31, 2013	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of March 31, 2013	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
590,047	8.09	\$0.71	454,435	7.87	\$0.74

As of March 31, 2013 (unaudited), the unrecognized stock-based compensation expense related to unvested stock options was approximately \$146,000 which is expected to be recognized over a weighted average period of approximately 20 months.

The aggregate intrinsic value of stock options outstanding and exercisable at March 31, 2013 (unaudited) was approximately \$1.3 million and \$1.1 million, respectively. This amount is before applicable income taxes and represents the market price of the Company's common stock at March 31, 2013 less the grant price, multiplied by the number of stock options that had a grant price that is less than the market price. This amount represents the amount that would have been received by the optionees had these stock options been exercised on that date. During the year ended March 31, 2013 (unaudited), the aggregate intrinsic value of stock options exercised was zero.

A summary of the activity of the Company's unvested stock options is as follows:

	Options	Weighted Average Grant Date Fair Value
Balance at January 1, 2011	93,343	\$ 0.37
Granted	334,031	0.37
Vested	(173,229)	0.37
Forfeited	(5,706)	0.41
Balance at December 31, 2011	248,439	\$ 0.39
Granted	178,742	1.31
Vested	(257,510)	0.83
Forfeited	(11,594)	0.64
Balance at December 31, 2012	158,077	\$ 0.97
Granted, (unaudited)	—	—
Vested, (unaudited)	(22,482)	0.94
Forfeited, (unaudited)	—	—
Balance at March 31, 2013, (unaudited)	<u>135,593</u>	<u>\$ 1.08</u>

The total fair value of shares vested for the years ended December 31, 2012 and 2011 was \$212,795 and \$63,010, respectively. The unaudited total fair value of shares vested for the three month periods ended March 31, 2013 and 2012 was \$20,993 and \$15,933, respectively.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

*Restricted Stock*

The following table summarizes restricted stock option activity at December 31, 2012 and 2011 and March 31, 2013 (unaudited):

	<u>Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested at January 1, 2011	42,941	\$ 0.48
Granted	—	\$ —
Vested	(31,347)	0.53
Cancelled	—	—
Unvested at December 31, 2011	11,594	\$ 0.64
Granted	—	\$ —
Vested	(8,696)	2.23
Cancelled	—	—
Unvested at December 31, 2012	2,898	\$ 2.23
Granted, (unaudited)	—	\$ —
Vested, (unaudited)	(2,174)	2.67
Cancelled, (unaudited)	—	—
Unvested at March 31, 2013, (unaudited)	<u>724</u>	<u>\$ 2.67</u>

At December 31, 2012 and March 31, 2013 (unaudited), unrecognized stock-based compensation expense related to unvested restricted stock was approximately \$6,467 and \$1,934, respectively, which is expected to be recognized over a weighted average period of approximately four and one months, respectively.

*Common Stock Warrants*

On March 10, 2011 the Company issued warrants to purchase 32,610 shares of common stock to non-employee placement agents in consideration for a private equity placement transaction. The warrants have an exercise price of \$0.48 per share and expire 10 years from the issuance date. The fair market value of the warrants was calculated on the grant date based on the Black-Scholes-Merton option pricing model, and the Company recorded \$12,434 of stock issuance costs for the year ended December 31, 2011.

**12. Income Taxes**

The components of income tax expense (benefit) attributable to continuing operations are as follows:

	<u>Year ended December 31,</u>	
	<u>2012</u>	<u>2011</u>
Current expense:		
Federal	\$ —	\$ —
State	—	—
Deferred expense (benefit):		
Federal	\$ —	\$ —
State	—	—
Total	<u>\$ —</u>	<u>\$ —</u>

**Heat Biologics, Inc. and Subsidiaries**  
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**Notes to Consolidated Financial Statements**

The differences between the Company's consolidated income tax expense attributable to continuing operations and the expense computed at the 34% United States statutory income tax rate were as follows:

	<u>Year ended December 31,</u>	
	<u>2012</u>	<u>2011</u>
Federal income tax expense at statutory rate	\$ (840,190)	\$ (718,468)
State and local income taxes, net of federal benefit	(105,170)	(93,678)
Non-deductible expenses	54,991	18,692
Prior-period true-up	(152,306)	—
Research & development credit	(57,293)	—
Increase in valuation allowance	1,099,968	793,454
	<u>\$ —</u>	<u>\$ —</u>

The income tax effects of temporary differences from continuing operations that give rise to significant portions of deferred income tax assets (liabilities) are presented below:

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Net operating loss carryforward	\$ 2,186,432	\$ 1,299,322
Research & development credit	189,350	—
Other	50,013	26,505
Valuation allowance	<u>(2,425,795)</u>	<u>(1,325,827)</u>
Deferred income taxes	<u>\$ —</u>	<u>\$ —</u>

During 2012, the Company's valuation allowance increased by \$1,099,968 at December 31, 2012. This increase was primarily due to the generation of additional net operating loss carryforwards and income tax credits.

The Company has approximately \$11,408,032 of federal and state operating loss carryforwards which begin to expire in 2023.

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 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 December 31, 2012 and 2011, the Company had no such accruals.

The Company files income tax returns in the United States and various state jurisdictions. The Company is subject to examination by taxing authorities for the tax years ended December 31, 2008 through 2012.



**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

**13. Commitments**

In January 2011, the Company entered into a twelve month lease agreement for office space commencing on January 1, 2011. The monthly base rent was \$3,500. The Company cancelled the lease as of July 2011, when operations moved to North Carolina. Rent expense, net of sublease rental income of \$2,750, related to this lease was \$22,250 for 2011, which includes base rent of \$24,500 and a \$500 cancellation fee.

In November 2011, the Company entered into a thirteen month lease agreement for office space commencing on January 1, 2012. The monthly base rent is \$3,870, which commences February 1, 2012. The lease term may be extended for an additional 24 months on substantially the same terms. Future minimum lease payments for the year ended December 31, 2013, under the above commitment, was \$3,870.

In connection with the convertible note agreement entered into on October 20, 2011 with a vendor for an amount up to \$950,000, the Company is required to use the vendor exclusively for the manufacture and supply of the material for the Company's Phase 3 clinical trials and commercialization efforts.

**14. Related Party Transactions**

In 2010, the Company issued convertible notes in the aggregate principal amount of \$926,000 to an investor, the managing member of which is a member of the Company's Board of Directors. In 2011, the Company issued additional convertible notes in the aggregate principal amount of \$1,347,709 to the same investor. In September 2011, all of the convertible notes were converted into 1,101,769 shares of Series A Preferred Stock.

The Chairman of the Company's Scientific and Clinical Advisory Board was paid \$18,750, \$43,750, and \$140,625 in consulting fees for the years ended December 31, 2012 and 2011 and the period from inception through December 31, 2012, respectively.

A member of the Company's Scientific and Clinical Advisory Board was paid \$0 and \$50,000 in consulting fees for the years ended December 31, 2012 and 2011, respectively. The consulting fees paid since inception was \$50,000.

A member of the Company's management was paid \$30,910, \$26,000, and \$70,910 in consulting fees for the years ended December 31, 2012 and 2011 and the period from inception through December 31, 2012, respectively.

The Company had a related party payable balance of \$0 and \$12,371 as of December 31, 2012 and 2011, respectively.

In April 2010, a related party entity advanced the Company \$12,500. Interest is calculated on the outstanding balance annually at 3.25%. As of December 31, 2012 and 2011, the outstanding balance was \$0 and \$12,500, respectively as the entire principal balance was paid in full during 2012. At December 31, 2012 and 2011, accrued interest on this payable was \$0 and \$686, respectively.

In June 2012, the Company sold its 92.5% ownership interest in Heat II to a related party in exchange for \$9,250 in cash and a receivable of \$296,224 to be paid in full in seven years from the date of the purchase. Interest accrues on the receivable at a rate of 6% per annum. At December 31, 2012, the Company also has a related party receivable from this entity for \$9,571 related to invoices received by the Company pertaining to expenses of Heat II incurred subsequent to the sale of Heat II.

In March 2013, two Board of Director members and the Chief Executive Officer each purchased 2,622 shares of the Company's Series B-1 Preferred Stock at a per share price of \$2.67 in its private placement that consummated in March 2013.

See additional related party transactions in Note 7, Convertible Notes Payable and Note 11, Stockholders' Deficit.

**Heat Biologics, Inc. and Subsidiaries**  
**(A Development Stage Company)**  
**Notes to Consolidated Financial Statements**

**15. Net Loss per Common Share**

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the periods. Fully diluted net loss per common share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. Common equivalent shares consist of stock options that are computed using the treasury stock method.

For the years ended December 31, 2012 and 2011 and three month periods ended March 31, 2013 and 2012 (unaudited), all of the Company's common stock options and warrants, preferred stock, and preferred stock warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

**16. Subsequent Events**

On April 5, 2013, the Non-Formula Line described in Note 8 that was initiated in January of 2013 was paid in full and then extinguished, and thus the collateral funds were returned to the investor.

On May 3, 2013, the Company and the holder of the October 20, 2011 convertible note agreed to extinguish the note, and both parties acknowledged that no further payments were to be made pursuant to the agreement or any other promissory note. At that time, the Company owed the holder \$694,479 including accrued interest. The holder of the convertible note agreed to extend the due date of the current payable in the amount of \$694,479 to the earlier of July 15, 2013 or when the Company receives additional financing of gross proceeds of \$2,500,000. If such financing does not occur prior to July 15, 2013 then one half of the payables owed as of July 15, 2013 shall be due July 15, 2013 and the balance shall remain payable until such a financing is consummated.

On May 29, 2013, the Company effected a 1-for-2.3 reverse stock split of its issued and outstanding shares of common stock. The reverse stock split resulted in an adjustment to the preferred stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retrospectively, where applicable, to reflect the reverse stock split. The Company filed a Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation which made the reverse stock split effective and authorized 50,000,000 shares of \$0.0002 par value common stock and 10,000,000 shares of \$0.0001 par value preferred stock.

On May 29, 2013, the Company entered into an agreement with the holders of its Series B Preferred Stock pursuant to which it agreed that the terms of the Stock Purchase Agreement dated as of March 25, 2013 between the Company and the holders of the Series B Preferred Stock will be amended such that upon consummation of a Qualified Public Offering, the investors of the Series B-1 Preferred Stock will be issued shares of the Company's common stock having an aggregate value of \$361,669 on such date and the Company's obligation to issue, and the investors obligation to purchase, Series B-2 Preferred Stock and warrants upon fulfillment of the conditions specified in our Stock Purchase Agreement with the investors will terminate.

On May 29, 2013, the Company entered into an amendment to its stock purchase warrants with North Carolina Biotechnology Center and Square 1 Bank pursuant to which the warrants previously issued to North Carolina Biotechnology Center that were exercisable for shares of Series A Preferred Stock were amended to be exercisable for a like number of shares of common stock.

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**2,272,727 Shares  
Common Stock**



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**PROSPECTUS**

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*Sole Book-Running Manager*  
**Aegis Capital Corp**

*Co-Manager*  
**Cantor Fitzgerald & Co.**

, 2013

Until , 2013, all dealers that buy, sell or trade our common stock may be required to deliver a prospectus, regardless of whether they are participating in this offering. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

We estimate that expenses in connection with the distribution described in this registration statement (other than brokerage commissions, discounts or other expenses relating to the sale of the shares by the selling security holders) will be as set forth below. We will pay all of the expenses with respect to the distribution, and such amounts, with the exception of the Securities and Exchange Commission ("SEC") registration fee, FINRA filing fee and NASDAQ listing fee are estimates.

SEC registration fee	\$ 4,511
FINRA registration fee	5,461
NASDAQ listing fee	50,000
Accounting fees and expenses	192,000
Legal fees and expenses	200,000
Printing and related expenses	8,623
Transfer agent fees and expenses	2,000
Non-accountable expense allowance	250,000
Miscellaneous	37,405
Total	<u>\$ 750,000</u>

#### Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

Our amended and restated certificate of incorporation provides for indemnification of our directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws provide for indemnification of our directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us, within the meaning of the Securities Act, against certain liabilities.

#### Item 15. Recent Sales and Issuances of Unregistered Securities.

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.

In March 2013, we issued an aggregate of 1,891,419 shares of our Series B-1 Preferred Stock to 20 investors for aggregate gross proceeds of \$5,050,090.

In August 2012, we issued a warrant to Square 1 Bank exercisable for 7,609 shares of our Series A Preferred Stock in connection with the loan and security agreement that was entered into. The warrants have an exercise price of \$4.83 and expire August 7, 2022.

In April 2012, May 2012, October 2012, and November 2012 we issued options exercisable for an aggregate of 178,742 shares of our common stock at an exercise price of \$0.76 per share to six individuals and two entities for services rendered.

In December 2011, we issued a warrant exercisable for 12,940 shares of our Series A Preferred Stock to the North Carolina Biotechnology Center in connection with its loan to the Company of \$250,000. The principal plus accrued interest was due on December 14, 2014 and the loan agreement accrued interest at a rate of 4.25% per annum. The warrant is exercisable for a period of ten years at a price per share of \$4.83, contains a cashless exercise feature and contains a weighted average price adjustment feature.

In December 2011, we issued 73,455 shares of Series A Preferred Stock to one investor for a purchase price of \$2.10 per share and aggregate proceeds of \$154,256.

In October and November 2011, we issued options exercisable for an aggregate of 70,873 shares of our common stock at an exercise price of \$0.64 per share to four individuals for services rendered.

In September 2011, one investor converted the outstanding debt owed to him that was evidenced by a convertible note into 123,939 shares of Series A Preferred Stock. The issuance qualified for exemption under Section 3(a)(9) of the Securities Act.

In September 2011, one investor converted the outstanding debt owed to him that was evidenced by a convertible note into 48,092 shares of Series A Preferred Stock. The issuance qualified for exemption under Section 3(a)(9) of the Securities Act.

In September 2011, one investor converted the outstanding debt owed to him that was evidenced by four convertible notes into 1,101,769 shares of Series A Preferred Stock. The issuance qualified for exemption under Section 3(a)(9) of the Securities Act.

In August 2011, May 2011, September 2010 and May 2010 we issued to one investor a convertible promissory note in the principal amounts of \$922,709, \$425,000, \$576,000 and \$350,000, respectively, all with an interest rate of 3% per annum accruing monthly and all of which were subsequently converted into 1,101,769 shares of Series A Preferred Stock at a conversion price of \$2.10 per share.

In June 2011 we issued a convertible promissory note in the principal amount of \$100,000 with an interest rate of 3% per annum accruing monthly to one investor, which was subsequently converted into 48,092 shares of Preferred Stock.

In March and April 2011, we issued options exercisable for an aggregate of 263,158 shares of our common stock at an exercise price of \$0.64 and \$0.71 per share to ten individuals for services rendered.

In March 2011, we granted warrants exercisable for an aggregate of 32,610 shares of our common stock to 5 individuals for services rendered in connection with a placement agency agreement we had with Paramount BioCapital, a company no longer in existence. The warrants are exercisable at \$0.48 per share, vested immediately upon exercise and expire on March 21, 2021.

In September and November 2010, we issued options exercisable for an aggregate of 78,266 shares of our common stock at exercise prices of \$0.48 per share to ten individuals for services rendered.

In May 2010, we issued one convertible promissory note to one investor in the principal amount of \$250,000 with an interest rate of 3% per annum accruing monthly, which was subsequently converted into 123,939 shares of Preferred Stock at a conversion price of \$2.10 per share.

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.

**Item 16. Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
1.1**	Form of Underwriting Agreement between Heat Biologics, Inc. and Aegis Capital Corp., as representative of the several underwriters
3.1*	Certificate of Incorporation filed on June 10, 2008
3.2*	Amended and Restated Bylaws, as currently in effect
3.3*	Amended and Restated Certificate of Incorporation filed on October 16, 2009
3.4*	Second Amended and Restated Certificate of Incorporation filed on December 16, 2011
3.5*	Third Amended and Restated Certificate of Incorporation, as currently in effect
3.6**	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on May 29, 2013
4.1*	2009 Stock Incentive Plan
4.2*	First Amendment of the 2009 Stock Incentive Plan
4.3*	Second Amendment of the 2009 Stock Incentive Plan
4.4*	Third Amendment of the 2009 Stock Incentive Plan
4.5*	Fourth Amendment of the 2009 Stock Incentive Plan
4.6*	Warrant issued to Square 1 Bank
4.7**	Warrant issued to North Carolina Biotechnology Center
4.8*	Specimen Common Stock Certificate of Heat Biologics, Inc.
4.9*	Form of Stock Purchase Agreement by and among Heat Biologics, Inc and the Series B investors (Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions have been filed with the Commission)##
4.10**	Form of Representative's Warrant
4.11**	Amendment to Stock Warrant with North Carolina Biotechnology Center
4.12**	Amendment to Stock Warrant with Square 1 Bank
5.1	Opinion of Gracin & Marlow, LLP
10.1*	License Agreement (UMJ110) between the University of Miami and Heat Biologics, Inc. effective February 18, 2011 ##
10.2*	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008 ##
10.3*	License Agreement (143) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 11, 2011 ##
10.4*	License Agreement (D-107) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 ##
10.5*	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 ##
10.6*	Promissory Note with North Carolina Biotechnology Center dated December 14, 2011
10.7*	Loan Agreement with North Carolina Biotechnology Center dated December 14, 2011
10.8*	Common Stock Subscription Agreement between the University of Miami and Heat Biologics I, Inc. dated July 7, 2009
10.9*	Employment Agreement with Jeffrey Wolf dated December 18, 2009
10.10*	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011
10.11*	Lease with Europa Center dated as of November 18, 2011
10.12*	Non-Exclusive Evaluation and Biological Material License Agreement with American Type Culture Collection effective April 12, 2011 ##
10.13*	Manufacturing Services Agreement with Lonza Walkersville, Inc. dated as of October 20, 2011
10.14*	Assignment and Assumption Agreement dated June 26, 2009
10.15*	Termination Agreement UM97-114 dated June 26, 2009
10.16*	Loan and Security Agreement with Square 1 Bank dated August 7, 2012
10.17**	Employment Agreement with Jennifer Harris dated November 3, 2011 and amendment thereto dated May 1, 2013
10.18*	Amendment to License Agreement (UM97-14) dated April 29, 2009
10.19*	First Amendment to Loan and Security Agreement with Square 1 Bank dated November 30, 2012
10.20*	Second Amendment to License Agreement (UMSS-114) dated August 11, 2009
10.21*	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011
10.22*	1 <sup>st</sup> Lease Modification Agreement dated December 19, 2012
10.23*	Form of Co Sale and First Refusal Agreement by and among Heat Biologics, Inc and the Series B investors
10.24*	Form of Voting Agreement by and among Heat Biologics, Inc. and the Series B investors
10.25*	Form of Investor's Rights Agreement by and among Heat Biologics, Inc. and the Series B investors
10.26*	Second Amendment to Loan and Security Agreement with Square 1 Bank dated January 14, 2013
10.27*	Third Amendment to Loan and Security Agreement with Square 1 Bank dated February 28, 2013
10.28*	Fourth Amendment to Loan and Security Agreement with Square 1 Bank dated March 19, 2013

10.29*	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013
10.30*	Fifth Amendment to the Loan and Security Agreement with Square 1 Bank dated April 18, 2013
10.31**	Employment Agreement with Matthew Czajkowski dated May 15, 2013
10.32**	Form of Lock-up Agreement
10.33**	Form of Agreement with Series B Preferred Stockholders to amend Stock Purchase Agreement
21.1*	Subsidiaries of Heat Biologics, Inc.
<a href="#">23.1</a>	Consent of BDO USA, LLP
23.2**	Consent of Gracin & Marlow, LLP (included in Exhibit 5.1)
24.1*	Power of Attorney

## Confidential treatment has been requested as to certain portions of this exhibit. The omitted portions have been filed with the Securities and Exchange Commission.

\* Previously filed with the Securities and Exchange Commission on May 6, 2013.

\*\* Previously filed with the Securities and Exchange Commission on May 30, 2013.

## Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§230.424 of this chapter);

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(f) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(h) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Company of expenses incurred or paid by a director, officer or controlling person of the Company in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Company will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



(i) The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Amendment No. 3 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chapel Hill, State of North Carolina, July 8, 2013.

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf  
Name: Jeffrey Wolf  
Title: Chairman and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Date: July 8, 2013  
By: /s/ Jeffrey Wolf  
Jeffrey Wolf  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: July 8, 2013  
By: /s/ Matthew Czajkowski  
Matthew Czajkowski  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: July 8, 2013  
By: /s/ John Monahan, Ph.D.\*  
John Monahan, Ph.D.  
Director

Date: July 8, 2013  
By: /s/ Michael Kharitonov, Ph.D.\*  
Michael Kharitonov, Ph.D.  
Director

Date: July 8, 2013  
By: /s/ Paul Belsky, MD\*  
Paul Belsky, MD  
Director

Date: July 8, 2013  
By: /s/ Edward B. Smith\*  
Edward B. Smith  
Director

\*By: /s/ Jeffrey Wolf  
as attorney-in-fact

GRACIN & MARLOW, LLP  
The Chrysler Building  
405 Lexington Avenue, 26th Floor  
New York, New York 10174  
Telephone (212) 907-6457  
www.gracinmarlow.com

July 8, 2013

The Board of Directors  
Heat Biologics, Inc.  
100 Europa Drive  
Chapel Hill, NC 27517

Gentlemen:

We have acted as counsel to Heat Biologics, Inc., a Delaware corporation (the "Company"), and are rendering this opinion in connection with the filing of a Registration Statement on Form S-1 (File No. 333-188365) (the "Registration Statement") by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration of the sale by the Company of (i) up to 2,613,636 shares (the "Shares") of common stock par value \$0.0002 per share (the "Common Stock"), including up to 340,909 shares of Common Stock for which the underwriters have been granted an over-allotment option; (ii) a warrant (the "Warrant") to purchase up to 113,636 shares of the Company's Common Stock (the "Warrant Shares"); and (iii) the Warrant Shares. The Shares and the Warrant Shares are to be sold by the Company pursuant to an underwriting agreement by and among the Company and Aegis Capital Corp. (the "Underwriting Agreement"), the form of which has been filed as Exhibit 1.1 to the Registration Statement.

We are acting as counsel for the Company in connection with the issue and sale by the Company of the Shares, the Warrant and the Warrant Shares. We have examined signed copies of the Registration Statement as filed with the Commission. We have also examined and relied upon the Underwriting Agreement, the Warrant, stock record books, minutes of meetings and actions of the stockholders and the Board of Directors of the Company as provided to us by the Company, the Certificate of Incorporation and the By-laws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinions hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

We express no opinion herein as to the laws of any state or jurisdiction other than the substantive laws of the State of New York as it relates to the Warrant, the General Corporation Law of the State of Delaware and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that: (i) the Shares have been duly authorized for issuance and, when issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, will be validly issued, fully paid and nonassessable; (ii) the Warrant has been duly authorized for issuance and, when executed and delivered by the Company, will be a valid and binding obligation of the Company in accordance with its terms; and (iii) the Warrant Shares have been duly authorized for issuance and, when issued and paid for in accordance with the terms and conditions of the Warrant, will be validly issued, fully paid and non-assessable.

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We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b) (5) of Regulation S-K under the Securities Act and to the use of our name therein and in the related Prospectus under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission. This opinion is expressed as of the date hereof, and we disclaim any undertaking to advise you of any subsequent changes in the facts stated or assumed herein or of any subsequent changes in applicable law.

Very truly yours,

*/s/ Gracin & Marlow, LLP*

Gracin & Marlow, LLP

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Heat Biologics, Inc. and Subsidiaries  
(A Development Stage Company)  
Chapel Hill, North Carolina

We hereby consent to the use in the Prospectus constituting a part of this Registration Statement of our report dated April 8, 2013, relating to the consolidated financial statements of Heat Biologics, Inc. and Subsidiaries, which is contained in that Prospectus.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP  
Raleigh, North Carolina

July 8, 2013