UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-35994

HEAT BIOLOGICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-2844103**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S Employer Identification Number)*
801 Capitola Drive **Durham, NC**	**27713**
(Address of Principal Executive Offices)	*(Zip Code)*

(919) 240-7133
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	**Name of each exchange on which registered**
Common Stock, $0.0002 par value per share	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes☐ No ☑

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

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	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☑
(Do not check if a smaller reporting company)			

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2016, was approximately $11,039,724 based on $0.71, the price at which the registrant's common stock was last sold on that date.

As of March 28, 2017 the issuer had 33,526,992 shares of common stock outstanding.

Documents incorporated by reference: None.

HEAT BIOLOGICS, INC.

FORM 10-K

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report in some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our," and "Heat," refer to Heat Biologics, Inc. and its subsidiaries.

Item 1. *Business*

Overview

We are an immuno-oncology company developing novel therapies designed to activate a patient's immune system against cancer utilizing an engineered form of gp96. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT*® (Immune Pan-Antigen Cytotoxic Therapy) and *ComPACT*™ (Combination Pan-Antigen Cytotoxic Therapy), form the basis of our product candidates. Our platform technologies address two synergistic mechanisms of action: activation and proliferation of CD8+ T cells, or "killer" T cells; and T cell co-stimulation. We believe the use of these technologies in combination with other immunotherapies has the potential to dramatically improve patient outcomes.

Using our *ImPACT*® platform technology, we have developed product candidates that consist of live, genetically-modified, irradiated human cancer cells which secrete a broad spectrum of tumor-associated antigens ("TAAs") together with a potent immune response stimulator called gp96. The secreted antigen-gp96/TAA complexes are designed to activate a patient's immune system to recognize and kill cancer cells that express the TAAs included in the product candidates, which we have selected to address the most prevalent TAAs present in the "tumor signature" of a specific cancer.

Our *ComPACT*™ platform technology enables us to combine a pan-antigen T cell activating vaccine and a T cell co-stimulator in a single product, offering the potential benefits of combination immunotherapy without the need for multiple independent biologic products. Using *ComPACT*™, we have engineered new product candidates that incorporate various ligand fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB, TL1A, etc.) into the gp96-Ig expression vector, resulting in a single product candidate that includes both a pan-antigen T cell priming vaccine and a T cell co-stimulator.

Using our platform technologies, we produce product candidates from allogeneic cell lines selected to express the broadest array of commonly shared tumor antigens for a specified type of cancer. Unlike autologous or "personalized" therapeutic vaccine approaches that require the extraction of blood or tumor tissue from each patient and the creation of an individualized treatment, our product candidates are fully allogeneic and do not require extraction of individual patient's material or custom manufacturing. As a result, our product candidates can be mass-produced and readily available for immediate patient use. Because each patient receives the same treatment, we believe that our immunotherapy approach offers logistical, manufacturing and other cost benefits compared to patient-specific or precision medicine approaches.

Our wholly-owned subsidiary, Zolovax, Inc. (“Zolovax”), is in preclinical studies to develop therapeutic and preventative vaccines to treat infectious diseases based on our gp96 vaccine technology, with a current focus on the development of a Zika vaccine in collaboration with the University of Miami. Other infectious diseases of interest include HIV, West Nile virus, Dengue and yellow fever.

Clinical Pipeline

Using our *ImPACT*® platform technology, we have developed two product candidates: HS-110 (viagenpumatucel-L) as a potential treatment for patients with non-small cell lung cancer (“NSCLC”), currently in combination with an anti-PD-1 checkpoint inhibitor, and HS-410 (vesigenurtacel-L) as a product candidate to treat non-muscle invasive bladder cancer (“NMIBC”). To date, we have administered in excess of 1,000 doses of HS-410 and HS-110 collectively in almost 200 patients, generating a favorable safety profile and low toxicities. We are currently conducting a Phase 1b trial of HS-110, in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with NSCLC and a Phase 2 trial of HS-410 in patients with NMIBC.

HS-110 (viagenpumatucel-L) – Non-Small Cell Lung Cancer

HS-110 (viagenpumatucel-L) is a biologic product candidate comprising a cancer cell line that has been genetically modified using our *ImPACT*® technology platform to secrete a wide range of cancer-associated antigens related to lung cancer bound to gp96 proteins. We believe that HS-110 has the potential to activate a T cell-mediated pan-antigen immune response that could be an effective treatment for patients with NSCLC.

We are conducting a Phase 2 clinical trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, to treat patients with NSCLC. The multicenter, open-label trial is expected to initially enroll 18 patients evaluable for baseline biopsy and is designed to accommodate cohort expansion up to 30 patients per arm (approximately 60 patients). The purpose of the trial is to evaluate the safety and efficacy of HS-110 in combination with nivolumab, an FDA approved anti-PD-1 checkpoint inhibitor, in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival. Trial enrollment is currently ongoing.

On March 21, 2017, we reported positive interim results for the Phase 2 trial evaluating HS-110 in combination with Bristol-Myers Squibb’s anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. ELISPOT results suggest that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients. Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions. No tumor reductions were observed in patients that did not mount an immune response to HS-110. The timing of immune response to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained. Furthermore, to-date 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort. Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported by Teng et al, Cancer Research 75(11) June 1, 2015 for existing data on nivolumab alone.

On March 13, 2017, we issued a press release announcing that we achieved the safety and efficacy endpoints for the Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo®), for the treatment of NSCLC and that the trial met the expansion criteria to advance into a Phase 2. Five out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of TIL at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point. The Data Monitoring Committee concluded that the positive safety profile, mechanistic evidence and encouraging signs of synergistic efficacy warranted expansion to a Phase 2 trial.

On December 6, 2016, we reported that 1-year results from the first eight trial patients showed that the HS-110/nivolumab combination was well tolerated with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in the HS-110/nivolumab combination compared to existing data on single agent nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy ("immune responders") had longer overall survival and better objective response rate than the non-immune responders, even though they had the same baseline immune function. Immune responders in the study saw a 50% objective response rate while non-immune responders saw a 0% objective response rate. Moreover, the immune responders had a better median overall survival than non-immune responders. The 1-year overall survival was 50% for the responders and 25% for the non-responders. Finally, immune responders also saw a better median overall survival at 12.7 months, than non-immune responders, who saw a median overall survival of 7.1 months. Researchers concluded that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors.

Heat also conducted a Phase 2 randomized, controlled trial using HS-110 in combination with cyclophosphamide versus chemotherapy alone in third-line and fourth-line NSCLC patients. This trial, which enrolled 66 off 123 patients, was discontinued in 2015 to allow Heat to instead focus on combinations with checkpoint inhibitors. Data from the Phase 2 clinical trial continues to accrue and will be reported in 2017. The trial was structured as a multicenter randomized study to evaluate the immune response, safety and efficacy endpoints of HS-110 when administered weekly for 12 weeks in combination with low-dose cyclophosphamide in an induction period followed by monotherapy HS-110 every nine weeks during maintenance for up to one year or until discontinuation from study treatment, whichever occurred first. Patients randomized to the comparator arm were treated with one chemotherapy regimen until progression. Blood samples were taken to evaluate the immune response and their correlation to overall survival, and where considered appropriate by the investigator, patients are invited to consent for pre- and post-treatment biopsies for exploratory biomarker analysis. The primary endpoint was overall survival; secondary endpoints follow objective responses and immune response.

The inventor of the *ImPACT*® technology that we licensed reported results in February 2013 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. In the study, 18 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 (defined as three, six-week treatment cycles). 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 injection site reactions and rash that were transitory and usually resolved in one to two weeks. We believe the results of this Phase 1 trial with HS-110 demonstrate that HS-110 is capable of generating a CD8-CTL IFN-γ immune response in patients with advanced NSCLC. Eleven of the fifteen patients (73%) who completed the first course of therapy with HS-110, exhibited a two-fold or greater increase in CD8 cells secreting interferon gamma (CD8-CTL IFN- γ). The estimated median survival of these eleven patients was 16.5 months (95% CI:7.1-20.0). In comparison, the 4 patients who failed to show increased CD8-CTL IFN-γ responses 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. In 7 of 18 treated patients tumor growth was stabilized, however no partial or complete tumor responses (e.g., reduction or disappearance of tumors) were observed in any of the 18 patients. 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 survived over four years since starting the therapy and another patient survived over three years since starting the therapy. These findings were consistent with multiple preclinical published studies on *ImPACT*® therapy.

HS-410 (vesigenurtacel-L) –Bladder Cancer

HS-410 (vesigenurtacel-L) is a biologic product candidate comprising a cancer cell line genetically modified using our *ImPACT*® technology platform to secrete a wide range of cancer antigens related to bladder cancer bound to gp96 molecules . We believe that HS-410 has the potential to activate a T cell mediated pan-antigen immune response that could be an effective treatment for patients with NMIBC.

We are currently conducting a Phase 2 trial evaluating HS-410 either alone or in combination with intravesical standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of high-risk NMIBC. Our Phase 2 trial will examine safety, tolerability, immune response and preliminary clinical activity of HS-410. The primary endpoint is one-year disease free survival.

On November 30, 2016, we announced that we presented topline data from the 94-patient Phase 2 trial at the Society of Urology Annual Meeting in San Antonio, Texas. Researchers reported that there were encouraging signs of anti-tumor activity as HS-410 generated a robust antigen-specific immune response to multiple tumor-associated peptides in treated patients, while there were no immune responses of this type in the placebo. However, these responses did not translate into clinical outcomes, and there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. To better assess the durability of the positive immunological responses, and in keeping with clinical trial guidance recently issued by International Bladder Cancer Group recommending a 2-year study duration for NMIBC trials, we will continue to monitor all patients enrolled in the study for an additional 12 months. At that time, we will make a final determination on whether to progress our bladder program into a Phase 3 trial.

In January 2016, we reported three-month interim data from the unblinded, monotherapy cohort of our company's ongoing Phase 2 trial of HS-410 for the treatment of NMIBC at the Phacilitate Immunotherapy World Conference. In the monotherapy arm, a series of weekly intradermal injections of HS-410 is being dosed as an alternative to BCG. Images of the bladder taken from several treated patients showed changes that resemble lymphoid (T cell rich) structures that we have observed in biopsy samples, which we believe indicates that HS-410 is generating an immune response as expected. Six out of seven patients in the 25-patient arm, who had reached the 3-month timepoint after treatment with HS-410 alone, remained recurrence free. One of those patients had *carcinoma in situ* (*CIS*) – the patient population believed to be least responsive to BCG – and that patient experienced a complete response.

In November 2015, we announced the results from our Phase 1 trial, evaluating the safety and immune response of HS-410, after surgery and treatment with BCG, in patients with high-risk NMIBC. In that trial, HS-410 exhibited a positive safety profile and was well-tolerated with no serious adverse events (SAEs) and no patients discontinuing the trial due to adverse events (AEs). 7 out of the 10 patients had no documented recurrence of cancer >1 year after treatment. 3 out of 4 patients with *CIS* did not experience a recurrence one year after treatment. In the study subjects, HS-410 elicited a broad-based (polyclonal) expansion of patient T cells and a high level of CD8+ tumor-infiltrating lymphocytes (TILs). Additionally, based on tissue samples taken from each patient, HS-410 shared 15 or more tumor antigens in common with those expressed on the patients' cancer cells, which we believe supports our belief that HS-410 has the ability to target a broad range of tumor antigens. These data confirm previous preclinical findings regarding the unique mechanism of action for HS-410. Moreover, third-party analysis of blinded samples from the trial demonstrated a strong correlation between baseline characteristics of TILs by T cell receptor (TCR) sequencing and clinical outcome. Specifically, the 7 patients who remained disease free after one year exhibited the greatest clonal expansion of intratumoral T cells (p-value 0.0126).

In March 2015, the U.S. Food and Drug Administration ("FDA") granted Fast Track designation for HS-410 for the treatment of NMIBC. The Fast Track program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of developments to support approval and eligibility for priority review depending on clinical data at the time of Biologics License Application ("BLA") submission. We believe that this designation will expedite our development of HS-410.

Recent Developments

On March 28, 2017, we completed an underwritten public offering of 5,000,000 shares of our common stock at a price to the public of $0.80 per share for gross proceeds of $4.0 million and estimated net proceeds to us of approximately $3.5 million after deducting underwriting discounts and commissions and other estimated offering expenses. In addition, on March 30, 2017, we issued 750,000 additional shares of common stock at the public offering price of $0.80 per share in connection with the underwriter's exercise of their over-allotment option for gross proceeds of $600,000 and estimated net proceeds to us of approximately $548,000 after deducting underwriting discounts and commissions.

On March 7, 2017, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with Pelican Therapeutics, Inc. ("Pelican") and certain stockholders of Pelican holding a majority of the outstanding shares (the "Majority Pelican Stockholders") to purchase shares of the outstanding capital stock of Pelican (the "Pelican Acquisition"). Pelican is a biotechnology company focused on the development and commercialization of monoclonal antibody and fusion protein-based therapies that are designed to activate the immune system. The Purchase Agreement provides that it is a condition to closing that the holders of at least 80% of the outstanding capital stock of Pelican on a fully diluted basis participate in the Pelican Acquisition. We and Pelican intend to provide all Pelican stockholders with the opportunity to participate in the Pelican Acquisition by executing a Joinder Agreement pursuant to which they will become a party to the Purchase Agreement and agree to sell at least 80% (and up to 100%) of their shares. In order to participate in the Pelican Acquisition, Pelican stockholders must return an executed Joinder Agreement and other related documents to Pelican by the closing of the transaction, which is currently expected to occur by April 30, 2017. The Majority Pelican Stockholders own 75.5% of the fully diluted Pelican shares and have agreed to backstop the Pelican Acquisition and sell additional shares of Pelican common stock in the Pelican Acquisition (up to 100% of their shares) in order to enable us to acquire 80% of the outstanding capital stock of Pelican on a fully diluted basis. As of the date hereof, stockholders of Pelican holding in excess of 80% of the outstanding capital stock of Pelican on a fully diluted basis, which includes the Majority Pelican Stockholders, have entered into Purchase Agreements and agreed to sell up to 100% of their shares in order to enable us to acquire 80% of the outstanding capital stock of Pelican on a fully diluted basis.

Subject to certain conditions, and in exchange for 80% of the outstanding capital stock of Pelican on a fully diluted basis, Heat has agreed at the closing of the Acquisition (the "Closing"): (i) to pay to the Pelican Stockholders that execute the Stock Purchase Agreement (the "Participating Pelican Stockholders") an aggregate of $500,000 (the "Cash Consideration"), and (ii) to issue to the Participating Pelican Stockholders 1,331,082 shares of Heat restricted common stock representing 4.99% of the outstanding shares of Heat common stock on the date of execution of the Purchase Agreement (the "Stock Consideration"), which issuance will be exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended. The Cash Consideration will be reduced by the amount by which certain of Pelican's accrued liabilities are not satisfied for less than $250,000. The Cash Consideration and Stock Consideration will be placed into escrow for a period of up to six months to secure certain indemnification and other obligations of Pelican and the Participating Pelican Stockholders in connection with the Acquisition. The Cash Consideration and the Stock Consideration, if not used to satisfy indemnification obligations, will be paid to the Participating Pelican Stockholders on a *pro rata* basis based on each such Participating Pelican Stockholder's equity interest in Pelican as compared to the aggregate Pelican equity interests held by all Participating Pelican Stockholders.

In addition to the payments described above, under the terms of the Purchase Agreement, Heat agreed to cause Pelican to make cash payments to the Participating Pelican Stockholders upon the achievement of the following clinical and commercialization milestones, as well as low single digit royalty payments and payments upon receipt of sublicensing income:

(1) $2,000,000 upon Pelican's dosing of the first patient in its first Phase 1 trial for an oncology indication;
(2) $1,500,000 upon Pelican's dosing of the first patient in its first Phase 2 trial for an oncology indication;
(3) $3,000,000 upon successful outcome of the first Phase 2 trial for an oncology indication;
(4) $6,000,000 upon Pelican's dosing of the first patient in its first Phase 3 trial for an oncology indication;
(5) $3,000,000 upon Pelican's dosing of the first patient in its first Phase 3 trial for a non-oncology indication;
(6) $7,500,000 upon successful outcome of the first Phase 3 trial for an oncology indication;
(7) $3,000,000 upon successful outcome of the first Phase 3 trial for a non-oncology indication;
(8) $7,500,000 upon acceptance of a Biologics License Application (BLA) submission for an oncology indication;
(9) $3,000,000 upon acceptance of a BLA submission for a non-oncology indication;
(10) $7,500,000 upon first product indication approval in the United States or Europe for an oncology indication;
(11) $3,000,000 upon first product indication approval in the United States or Europe for a non-oncology indication; and

Pelican has been awarded a $15.2 million grant to fund preclinical and some clinical activities from the Cancer Prevention and Research Institute of Texas ("CPRIT"). The CPRIT grant is subject to customary CPRIT funding conditions. Heat intends to lend Pelican up to $910,231 to satisfy Pelican's matching fund obligation under the CPRIT Grant that will allow it to access the first year of the CPRIT grant funding in the amount of $1,820,462 and has agreed to loan Pelican approximately $250,000 to pay Pelican's legal fees and expenses incurred in connection with the Acquisition.

The Purchase Agreement contains customary representations, warranties and covenants of Heat, Pelican and the Participating Pelican Stockholders. Subject to certain customary limitations, the Participating Pelican Stockholders have agreed to indemnify Heat and its officers and directors against certain losses related to, among other things, breaches of Pelican's and the Participating Pelican Stockholders' representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Purchase Agreement.

In connection with the Acquisition, it is a condition to closing that Heat and the Participating Pelican Stockholders enter into a Stockholders' Agreement (the "Stockholders' Agreement") with respect to the Pelican common stock retained by the Participating Pelican Stockholders (the "Retained Shares"). The Stockholders' Agreement contains restrictions on transfer of the Retained Shares and drag-along rights in the event of a consolidation or merger of Pelican with another entity after the date of the Purchase Agreement or the sale of all or substantially all of Pelican's assets or a transaction in which at least fifty percent (50%) of the voting rights attached to the Pelican securities are sold. In addition, Participating Pelican Stockholders will have co-sale rights in connection with Heat's transfer of the Pelican Shares that Heat owns.

Pelican's lead product candidate is PTX-25, a humanized monoclonal antibody, and its second product candidate is PTX-15, a fusion protein. These agents target a pair of tumor necrosis factor (TNF) molecules known as TL1A and TNFRSF25. We believe these two molecules can provide precise control of inflammatory responses. PTX-25 targets TNFRSF25 and is intended for use in oncology patients and falls into an emerging class of oncology compounds known as 'Immuno-Oncology' agents. PTX-25 is a T cell costimulator that we believe has advantages over other compounds in development by several large pharmaceutical companies. PTX-15 is a follow-on product that we believe can provide precise control of the regulatory arm of our immune system and can be used in immuno-oncology or to prevent inflammation in autoimmune disease and transplantation.

Pelican's cancer therapy solution is to harness the body's natural tolerance mechanisms to develop therapies that reprogram the immune system and provide a long-term, durable effect after a short course of therapy. Pelican's therapies are based upon its understanding of the immune system and the mechanisms it uses to generate an immune system response employing the inbuilt tolerance mechanisms of the body's immune cells (i.e., a tolerogenic response). Classical immunogenic responses are initiated when antigen-presenting cells (APCs) present an antigen to CD4+ T helper (Th) lymphocytes, resulting in T cell activation, proliferation, and differentiation of effector Th1 and Th2 lymphocytes. In the classical immune response, Th1 and Th2 cells dominate over T-regulatory cells and initiate antigen removal. Similarly, tolerance induction begins with the same initial steps of the pathway (i.e., antigen presentation and T cell activation), but the abundance of antigen, how it is presented to the T cell, and the availability of CD4+ cell assistance can lead to the proliferation of a new class of lymphocytes called T-regulatory cells. Just as Th effector cells mediate a classical immune response, T-regulatory cells are the mediators of a tolerogenic response. The dominance of T-regulatory cells over effector cells results in antigen preservation and immunological tolerance. Pelican is developing therapies that deliberately shift the balance of these reciprocating immune responses to achieve a specific therapeutic effect. As these therapies are based on natural, existing components of the immune system, Pelican expects they will be safer, longer-lasting, and more effective than traditional medicines after only a short course of therapy.

Additional Indications

We continue to evaluate other potential indications for our*ImPACT*® and *ComPACT*™ platform technologies. Specifically, using *ComPACT*™, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy for non-small cell lung cancer (HS-120). Our decision to further pursue these product candidates or any additional product candidates other than our two lead product candidates will be based in part upon available funding and partnering opportunities.

On February 18, 2015, we announced a collaboration with OncoSec Medical Inc. to evaluate the feasibility of OncoSec's ImmunoPulse*in vivo* electroporation technology for intra-tumoral delivery of gp96-Ig encoding DNA plasmids to activate specific immune responses against 'private,' mutation-derived tumor neo-antigens. In April 2016, we announced the first preclinical data from this collaboration. Preclinical data demonstrated that combining Heat's *ComPACT* vaccine with OncoSec's intratumoral DNA electroporation delivery platform stimulated an expansion of neoantigen-specific CD8+ T cells, leading to a regression in both treated and untreated cancer tumors in two mouse studies (melanoma and colorectal cancer). These findings provide initial proof-of-principal and warrant further investigation.

ComPACT™

On June 15, 2015, we announced the development of a next-generation platform incorporating various T cell costimulatory ligand fusion proteins into the gp96-Ig expression vector. *ComPACT*™ combines a pan-antigen T cell priming vaccine and T cell co-stimulator in a single product, offering the potential benefits of combination immunotherapy in a single drug without the need for multiple independent biologic products. *ComPACT*™ has been engineered to incorporate various ligand fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB, TL1A, etc.), enabling the combination of two important immunotherapy pathways in a single drug. We have reported preclinical data demonstrating that *ComPACT*™ secreting OX40L generated the most potent immune response among other *ComPACT*™ co-stimulator variations including TL1A, 4-1BBL and ICOSL, as well as compared to systemic delivery of OX40 agonist antibody and vaccine alone.

ImPACT® Therapy

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 may enable the body to activate 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 preclinical 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 combat a wide range of cancers and infectious diseases. 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 final 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.

***ImPACT*® / *ComPACT*™ Platform Technologies Advantages**

- *ImPACT*® therapy represents a cell-based product platform that functions as both an immune activator and an antigen-delivery vehicle for the proliferation of antigen-specific T cells.
- In addition, to our knowledge *ImPACT*® is the only adjuvant currently in clinical development that is specific to CD8+ cytotoxic T cell immune responses, which we believe is especially important for developing therapeutics in oncology.
- *Our therapies do not require an additional adjuvan*.. 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.
- *ComPACT*™ represents a potential dual-acting immunotherapy, combining a pan-antigen T cell priming vaccine and T cell co-stimulator in a single product.
- To our knowledge, *ComPACT*™ represents the first dual-acting immunotherapy that provides more effective stimulation of CD8+T cells and higher rates of tumor rejection than are achieved with either individual administration of traditional vaccines, OX40 agonist antibodies, or combinations with OX40 agonist antibodies and traditional vaccines.

The CD8+ cytotoxic T cell specific nature of our *ImPACT*® and *ComPACT*™ platform technologies predict that they will be most useful in stimulating immune responses for diseases where actual cell-killing is an important part of the therapeutic effect. Cancer, which is a disease of mutated proliferating cells, naturally became the first area of focus. *ImPACT*® and *ComPACT*™ applied to cancer therapies contrast in several critical ways to other cancer immunotherapy technologies:

- Both *ImPACT*® and *ComPACT*™ platform technologies offer our ready-to-use/off-the-shelf approach which do not require any personalized manufacturing. We believe our allogeneic 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.

- Both *ImPACT*® and *ComPACT*™ platform technologies have been shown to stimulate an immune response against the full antigenic repertoire of the cancer cells, not just one or a handful of antigens. Our *ImPACT*® and *ComPACT*™ platform technologies are designed to combine broad antigen targeting of known and unknown tumor associated antigens complexed with a potent immune adjuvant. The activated immune response generated by our platform technologies may be useful in treating a wide range of cancers and infectious diseases.

- There are no other allogeneic, cell-based vaccine technologies known to us which provide a molecular transporter (gp96-Ig in the case of*ImPACT*® and *ComPACT*™) to provide specific activation of a patient's CD8+ T cells across MHC barriers.

Our Corporate Background

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. Our website address is www.heatbio.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not a part of this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the U.S. Securities and Exchange Commission (the "SEC"). The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the Audit Committee, Compensation Committee, Nominating Committee, Strategic Planning Committee and Science and Technology Committee of the Board of Directors. Our phone number is (919) 240-7133 and our facsimile number is (919) 305-8566. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street NE, Room 1580 Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

References to Heat Biologics also include references to our subsidiaries Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd., and Zolovax Inc. unless otherwise indicated. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. Heat formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012. Heat also formed Heat Biologics Australia Pty LTD, a wholly-owned company, registered in Australia on March 14, 2014. On October 25, 2016 Heat formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, dengue and yellow fever. We assigned our proprietary rights related to the development and application of our *ImPACT*® therapy platform to Heat Biologics I, Inc. In June 2012, we divested our 92.5% interest in Heat Biologics II, Inc.

Strategy

Our objective is to become a leading biopharmaceutical company specializing in the development and commercialization of allogeneic, ready-to-use immunotherapies. Our platform technologies, *ImPACT*® and *ComPACT*™, are designed to address two synergistic mechanisms of action: robust activation of killer T cells and T cell co-stimulation to further enhance patients' immune response and immune memory. We believe future cancer immunotherapy will involve multiple agents and our platform could work synergistically with other therapies, such as checkpoint inhibitors, which are designed to reverse tumor-induced immune suppression. We are focused on discovering, developing and applying our *ImPACT*® and *ComPACT*™ platform technologies in combination with other immunotherapies towards a number of disease indications. The key elements of our strategy are:

- *Develop and obtain regulatory approval for our product candidates.* We are conducting a Phase 2 trial of HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, to treat patients with NSCLC, and a Phase 2 trial of HS-410 in combination with BCG for the treatment of NMIBC. Beyond NSCLC and bladder cancer - depending upon funding and partnering opportunities - we plan to initiate additional clinical trials and in some cases expand current clinical trials in these and other disease targets utilizing our *ImPACT*® and *ComPACT*™ platform technologies.

- *Maximize commercial opportunity for our ImPACT® and ComPACT™ technology.* Our current 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 commercialization efforts.

- *Enhance our partnering efforts.* We are continually exploring partnerships for licensing and other collaborative relationships and remain opportunistic in seeking strategic 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 six different patent families directed to therapeutic compositions and methods related to our vaccine platform and preclinical development programs for cancer and have filed certain additional patent applications that are owned by us. Our *ImPACT®*/*ComPACT™* patent portfolio comprise more than fifty issued patents and ten 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 non-dilutive grant funding.* To more fully develop our *ImPACT®* and *ComPACT™* platform technologies and their 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 and other 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®* and *ComPACT™* platform technologies. We plan to continue to leverage our 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 1.69 million people in the United States will be diagnosed with cancer in 2017. The lifetime probability of being diagnosed with an invasive cancer is 41% for men and 38% for women. It is projected that 600,920 Americans will die from cancer in 2017.

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 2004 and 2010 is an average of 68%. According to the Centers of Disease Control and Prevention, in 2011, cancer was the second leading cause of mortality in the United States (22.9%) behind heart disease (23.7%). The American Cancer Society estimates that one in four deaths in the United States 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 new treatments 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 externally, or 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 and/or receiving grant funding, the success of HS-110 and HS-410 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 HS-410 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*® and *ComPACT*™ platform technologies are forms 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*® and *ComPACT*™-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 can eventually become life threatening. Our therapeutic vaccines are designed to assist the immune system in identifying and eliminating malignant cells. Our approach involves activating strong T cell immune responses against cellular antigens that are characteristic of malignant cells with the goal of destroying the cancer expressing those antigens.

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 and multiply 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 disease-related cells will escape detection by the immune system and immunotherapy.
- Many active immunotherapies employ a single defined antigen so they are not effective against cancers which do not express that antigen.
- Most immunotherapies produce toxic effects resulting in damage to healthy tissues.
- 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.

Although many of the immunotherapies currently in clinical development have shown promising results, we believe that specific proprietary elements of the *ImPACT*® and *ComPACT*™ platform technologies combined with a well-honed clinical strategy position Heat favorably in the marketplace.

Our Solution: ImPACT®/ComPACT™ Therapy

We believe our *ImPACT*® and *ComPACT*™ therapies have 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:

- They are designed to fight cancer by activating the immune system against a wide variety of cancer antigens (both known and unknown). This has now been confirmed in patients with non-muscle invasive bladder cancer treated with HS-410.
- They are 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.
- They are 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*® and *ComPACT*™ product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies.
- Our *ImPACT*® therapy represents an agent that functions as both an immune activator and an antigen-delivery vehicle. To our knowledge *ImPACT*® is the only allogeneic cell-based technology platform currently in clinical development that is specific to CD8+ cytotoxic T cell immune response, which is especially important for developing therapeutics in oncology.
- Our *ComPACT*™ platform was developed using in-house expertise and is a platform that can provide a vaccine and a T cell costimulatory molecule in a single therapeutic. In preclinical studies, the *ComPACT*™ platform incorporating OX40 stimulation provided superior immune response and tumor rejection to what is seen with either OX40 agonist antibodies alone or in combination with traditional vaccines.
- Our *ImPACT*® and *ComPACT*™ platforms are off-the-shelf therapies and offer substantial manufacturing and cost advantages compared to autologous or "personalized" immunotherapies.

ImPACT® TECHNOLOGY PLATFORM

ImPACT® Background

Our *ImPACT*® technology represents an "off-the-shelf" method to deliver cancer antigens complexed to 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 "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. This characterizes the role of HSPs as damage associated molecular patterns (DAMPS). 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.

HSPs have several functions including:

- Protecting tissues from pathogens by activating the immune system.
- Acting as a chaperone to:
  - Facilitate proper protein folding within the endoplasmic reticulum.

- Enable proper function of toll-like receptors and the innate immune system.
- Carry damaged proteins to intracellular garbage disposals to be degraded into peptides (short chains of amino acids– that are 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.

· Directing antigen cross presentation for activation of CD8+ T cells toward tumor antigens.

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 and it is able to recognize all antigens. It also induces the immune system to activate and multiply 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 secrete 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, M.D., Ph.D., the former Chairman of our Scientific Advisory Board and the inventor of this technology, deleted this KDEL sequence and replaced it with another sequence that causes the new fusion protein, called gp96-Ig, to be secreted 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 antigens. Dr. Podack demonstrated 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.

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 20 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. 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 cells.

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

A single type of tumor 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 tumor-cell line, we believe that *ImPACT®'s* technology can develop a therapy that shares many common features with patients' tumors. 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 (also known as a helper 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, **our patented approach uses modified heat shock proteins to stimulate an immune response against multiple antigens contained within cancer cells (both known and unknown).** Cancer cells express different antigens that can be used to initiate an immune response. Each *ImPACT*® vaccine is created from a tumor-cell line that we believe expresses a wide array of those antigens most commonly expressed in a particular type of cancer. For our lung cancer trials, the cell line that was used and expressed the most favorable antigen profile for lung cancer was a lung cancer cell line and for our bladder cancer trials the cell line that was used and expressed the most favorable antigen profile for bladder cancer was a prostate cancer cell line. We believe this "pan-antigen" approach provides each patient with a higher likelihood of a response to the therapy.

(ii) Our product candidates are made from "off-the-shelf" (allogeneic) cells and may therefore be **less expensive to manufacture than patient-specific (autologous) vaccines**. Our 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, our *ImPACT*® technology is the only "off-the-shelf" (allogeneic) vaccine – to our knowledge – 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 *ComPACT*™ Technology Platform

The *ComPACT*™ technology platform was created in-house to take advantage of all aspects of the T cell activation platform and to build upon them. Because the future of cancer immunotherapy appears to be focused on drug combinations, it is valuable to conceive technologies where one drug may be re-purposed to do two things, rather than always relying on individual combinations of different single-function drugs. The need for this sort of innovation is highlighted by the approval of Nivolumab and Yervoy for patients with late stage melanoma. The price for this combination is greater than $250,000 per course of therapy, not including the substantially increased ancillary costs associated with monitoring and treating the potentially fatal complications that are common with such a combination. *ComPACT*™ was designed to deliver the gp96-Ig vaccine molecule together with a T cell costimulatory fusion protein in a single compound. The first iterations of *ComPACT*™ included OX40L-Fc, 4-1BBL-Fc and ICOSL-Fc as the T cell costimulatory proteins, and due to preferential activity with the OX40L-Fc version of *ComPACT*™, this compound has been selected for clinical development. Interestingly, the activity of locally secreted OX40L-Fc from *ComPACT*™ provides a superior immune response and tumor rejection than what is seen with OX40 agonist antibodies.

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-muscle invasive bladder cancer ("NMIBC") and non-small cell lung cancer ("NSCLC"). The inventor of our technology platform had also completed a study in primates for the development of a therapeutic and prophylactic vaccine for the treatment and prevention of HIV. This study was 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 at 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 with any such research to further clinical trials and incorporate such research into our future development plans.

***ImPACT*® INDICATIONS**

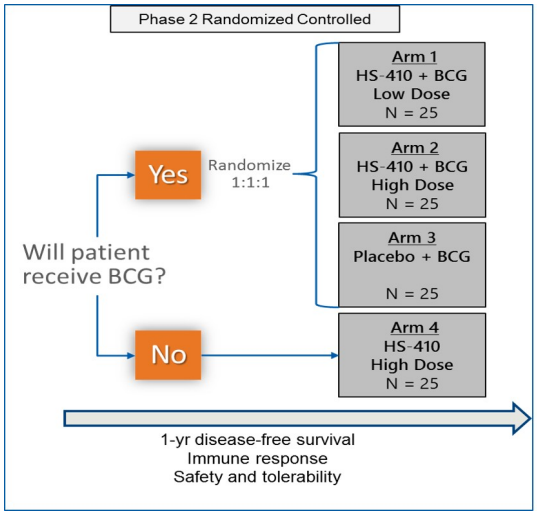
Bladder Cancer

Disease

In the United States, bladder cancer is the fifth most common type of cancer. In 2017, the American Cancer Society estimates 79,030 cases of bladder cancer will be diagnosed in the United States, and an estimated 16,870 deaths will occur. According to the American Cancer Society there are currently over 500,000 bladder cancer patients in the United States and thirty percent (30%) of the patients have muscle invasive bladder cancer ("MIBC") and seventy percent (70%) of the patients have NMIBC. Available treatments are currently not effective, in all patients, thus this remains an area of high unmet need. According to Park JC, et al. *Clin Adv Hematol Oncol.* 2014 Dec;12(12):838-45, lifetime treatment costs are $96,000 to $187,000 per individual per year in U.S.

Phase 2 Clinical Development

Enrollment is complete for the 78 patients in the blinded, randomized, placebo-controlled arms of our Phase 2 clinical 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. We enrolled an additional 16 patients to evaluate HS-410 as a monotherapy in an unblinded, open-label arm. The Phase 1 portion started treatment with HS-410 after standard intravesical bacillus Calmette-Guérin (BCG) immunotherapy; the Phase 2 portion investigates one of two doses of HS-410 or placebo in combination with BCG or one dose of HS-410 as monotherapy.



Fast track designation by FDA

Design

- Dosing regimen 12 week induction followed by maintenance according to BCG schedule

Operations

- Multi-center trial of ~16 sites in U.S.
- Lead center: University of Chicago School of Medicine
- Positive safety profile with no SAEs
- Complete enrollment 4Q:15
- Data readout 4Q:16

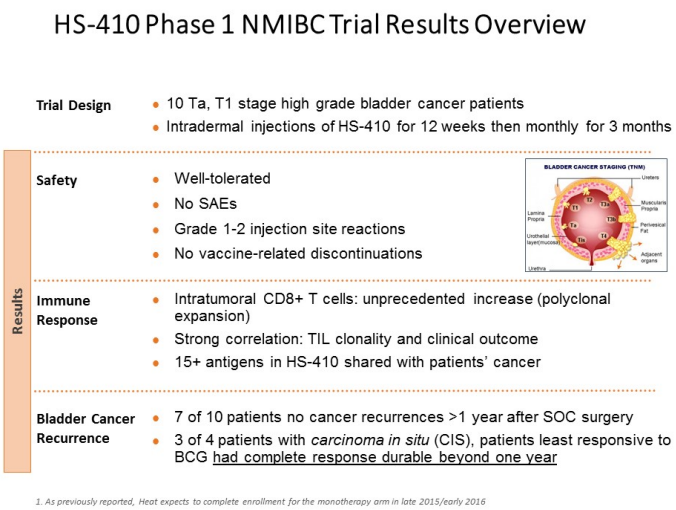
Patient Population

- NMIBC (Ta, T1, CIS)
- Newly diagnosed or >12mo from BCG

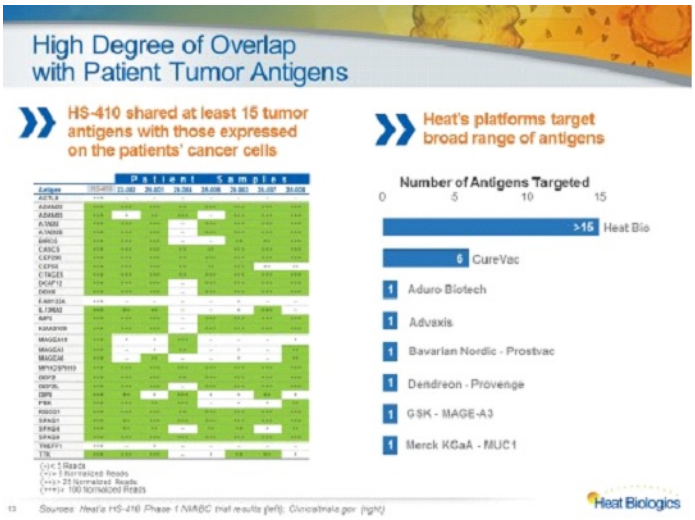
On November 30, 2016, we announced that we presented topline data from the 94-patient Phase 2 trial at the Society of Urology Annual Meeting in San Antonio, Texas. Researchers reported that there were encouraging signs of anti-tumor activity as HS-410 generated a robust antigen-specific immune response to multiple tumor-associated peptides in treated patients, while there were no immune responses of this type in the placebo. However, these responses did not translate into clinical outcomes, and there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. To better assess the durability of the positive immunological responses, and in keeping with clinical trial guidance recently issued by International Bladder Cancer Group recommending a 2-year study duration for NMIBC trials, we will continue to monitor all patients enrolled in the study for an additional 12 months. At that time, we will make a final determination on whether to progress our bladder program into a Phase 3 trial.

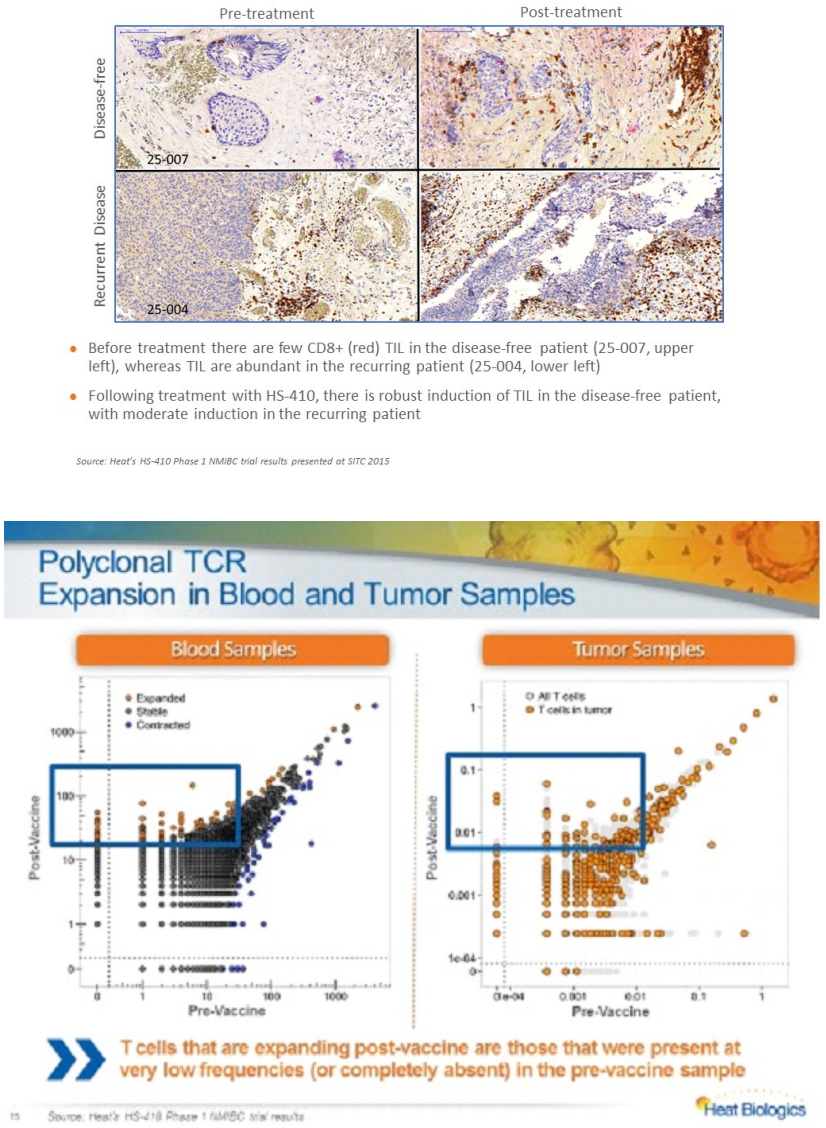
In January 2016, we reported three-month interim data from the unblinded, monotherapy cohort of the company's ongoing Phase 2 trial of HS-410 for the treatment of NMIBC at the Phacilitate Immunotherapy World Conference. In the monotherapy arm, a series of weekly intradermal injections of HS-410 is being dosed as an alternative to BCG. Images of the bladder taken from several treated patients showed changes that resemble lymphoid (T cell rich) structures that we have observed in biopsy samples, which we believe indicates that HS-410 is generating an immune response as expected.

In November 2015, we announced results from our Phase 1 trial, evaluating the safety and immune response of HS-410, after standard of care, BCG, for the treatment of high risk NMIBC. These results are outlined below:



HS-410 exhibited a positive safety profile and was well-tolerated with no patients discontinuing the trial due to adverse events (AEs). Furthermore, no serious adverse events (SAEs) were reported, and 7 out of 10 patients had no documented recurrence of cancer >1 year after standard of care surgery. Significantly, 3 out of 4 patients with *carcinoma in situ* (CIS), the patient population least responsive to standard of care, did not recur. HS-410 elicited a broad-based (polyclonal) expansion of patient T cells and a high level of CD8+ tumor-infiltrating lymphocytes (TILs). Additionally, based on tissue samples taken from each patient, HS-410 shared 15 or more tumor antigens in common with those expressed on the patients' cancer cells, which we believe indicates HS-410's ability to target a broad range of tumor antigens for all patients treated to date. These data confirm previous clinical findings regarding the unique mechanism of action for HS-410 and for our *ImPACT*® and *ComPACT*™ platform technologies. Moreover, third-party analysis of blinded samples demonstrated a strong correlation between baseline characteristics of TILs by T cell receptor (TCR) sequencing and clinical outcome. Specifically, the 7 patients who remain disease free exhibited the greatest clonal expansion of intratumoral T cells (p-value 0.0126).





On March 5, 2015, we were notified that the U.S. Food and Drug Administration ("FDA") granted Fast Track designation for HS-410 for the treatment of NMIBC. The Fast Track program is designed to facilitate the development and expedite the review of therapies intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. The advantages of Fast Track designation include actions to expedite development, including opportunities for frequent interactions with the FDA review team to discuss all aspects of developments to support approval and eligibility for priority review depending on clinical data at the time of Biologics License Application ("BLA") submission. We believe that this designation will expedite our development of HS-410.

Lung Cancer

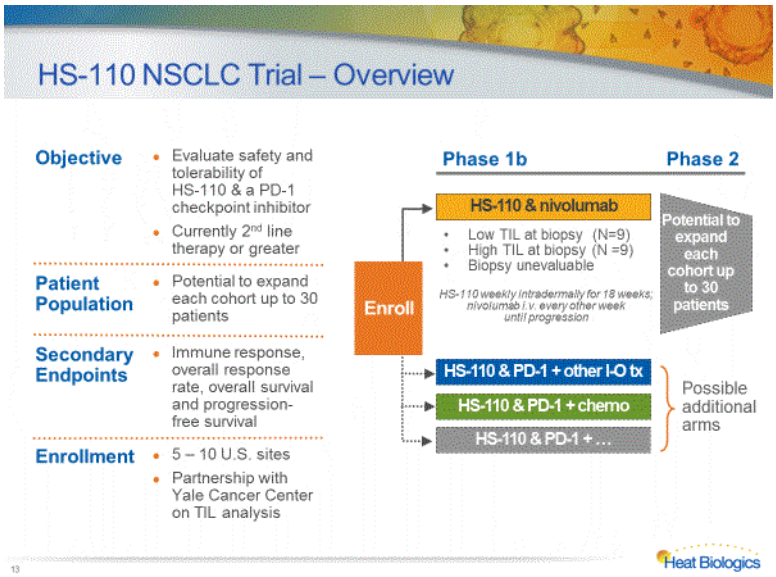
Disease

Lung cancer is the leading cause of cancer-related death in the United States. According to the National Cancer Institute, in 2015, lung cancer was expected to account for 26% of all female cancer deaths and 28% of all male cancer deaths. An expected 222,500 people will be diagnosed with lung cancer in the United States in 2016. Of these lung cancers, roughly 85% were expected to present as non-small cell lung cancer. Patients with advanced clinical stage IIIB/IV disease have a 5-year survival rate as low as 1-5%.

Phase 1b/2 Clinical Trial

In May 2015, we initiated our Phase 1b/2 clinical trial investigating the combination of our HS-110 therapeutic vaccine and nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with non-small cell lung cancer (NSCLC). HS-110 is our first product candidate in a series of proprietary *ImPACT*® based immunotherapies designed to stimulate patient's own T cells to attack cancer. HS-110 is a biologic product comprising 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 gp96 proteins and activate a T cell mediated pan-antigen immune response against the patient's cancer. This multicenter trial is evaluating the safety and efficacy of HS-110 in combination with nivolumab in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival. The trial is structured as a Phase 1b/Phase 2 with pre-specified thresholds in place to expand the trial to a full Phase 2. This trial is expected to initially enroll 18 patients evaluable for baseline biopsy and is designed to accommodate cohort expansion up to 30 patients per arm (approximately 60 patients). Trial enrollment is currently ongoing.

Phase 2 HS-110 Trial Design



On March 21, 2017, we reported positive interim results for the Phase 2 trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. ELISPOT results suggest that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients. Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions. No tumor reductions were observed in patients that did not mount an immune response to HS-110. The timing of immune response to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained. Furthermore, to-date 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort. Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported by Teng et al, Cancer Research 75(11) June 1, 2015 for existing data on nivolumab alone.

On March 13, 2017, we issued a press release announcing that we achieved the safety and efficacy endpoints for the Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo®), for the treatment of NSCLC and that the trial met the expansion criteria to advance into a Phase 2. Five out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of TIL at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point. The Data Monitoring Committee concluded that the positive safety profile, mechanistic evidence and encouraging signs of synergistic efficacy warranted expansion to a Phase 2 trial.

On December 6, 2016, we reported that 1-year results from the first eight trial patients showed that the HS-110/nivolumab combination was well-tolerated with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in HS-110/nivolumab combination compared to existing data on single agent nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy ("immune responders") had longer overall survival and better objective response rate than the non-immune responders, even though they had the same baseline immune function. Immune responders in the study saw a 50% objective response rate while non-immune responders saw a 0% objective response rate. Moreover, the immune responders had a better median overall survival than non-immune responders. The 1-year overall survival was 50% for the responders and 25% for the non-responders. Finally, immune responders also saw a better median overall survival at 12.7 months, than non-immune responders, who saw a median overall survival of 7.1 months. Researchers concluded that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors.

Phase 2 Clinical Development

Heat conducted a Phase 2 randomized, controlled trial using HS-110 in combination with cyclophosphamide versus chemotherapy alone in third-line and fourth-line NSCLC patients. This trial, which enrolled 66 of 123 patients, was discontinued in 2015 to allow Heat to instead focus on combinations with checkpoint inhibitors. Data continue to accrue and will be reported in 2017.

The trial was structured as a multicenter randomized study to evaluate the immune response, safety and efficacy endpoints of HS-110 when administered weekly for 12 weeks in combination with low-dose cyclophosphamide in an induction period followed by monotherapy HS-110 every nine weeks during maintenance for up to one year or until discontinuation from study treatment, whichever occurred first. Patients randomized to the comparator arm were treated with one chemotherapy regimen until progression. Blood samples were taken to evaluate the immune response and their correlation to overall survival, and where considered appropriate by the investigator, patients are invited to consent for pre- and post-treatment biopsies for exploratory biomarker analysis. The primary endpoint was overall survival; secondary endpoints follow objective responses and immune response.

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. The Phase 1 trial was conducted under an investigator-sponsored IND and was fully funded by the NIH.

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.

We believe that the results of the Phase 1 trial with HS-110 demonstrate that HS-110 is capable of generating a CD8-CTL IFN-γ 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- γ). 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. There were no objective tumor responses. The median one-year overall survival rate of patients in the study was 44% (95% CI:21.6-65.1).

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. The single grade 3 AE was in the “Body as a Whole” category (fatigue) and was rated as “possibly” related. 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.

Adverse Events by Body System

Body System	**Number of Events (N=219)**	**Severity Grade (# of events)**
Injection 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) [a] Grade 3(1) [b]
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.

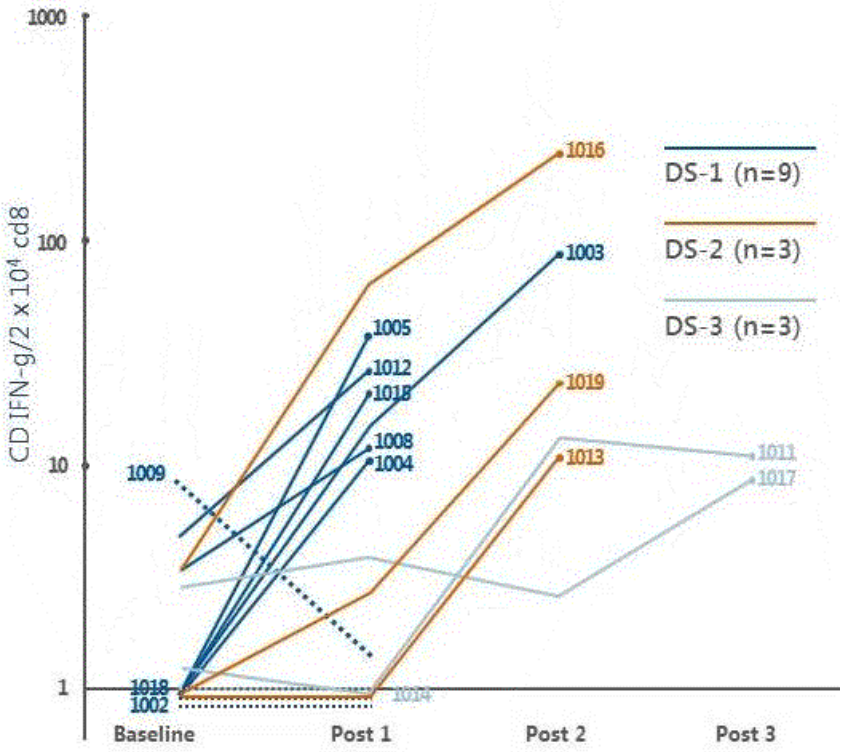
b The single grade 3 AE was in the body as a whole category (fatigue) and was rated as possibly related.

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- γ) following vaccination.

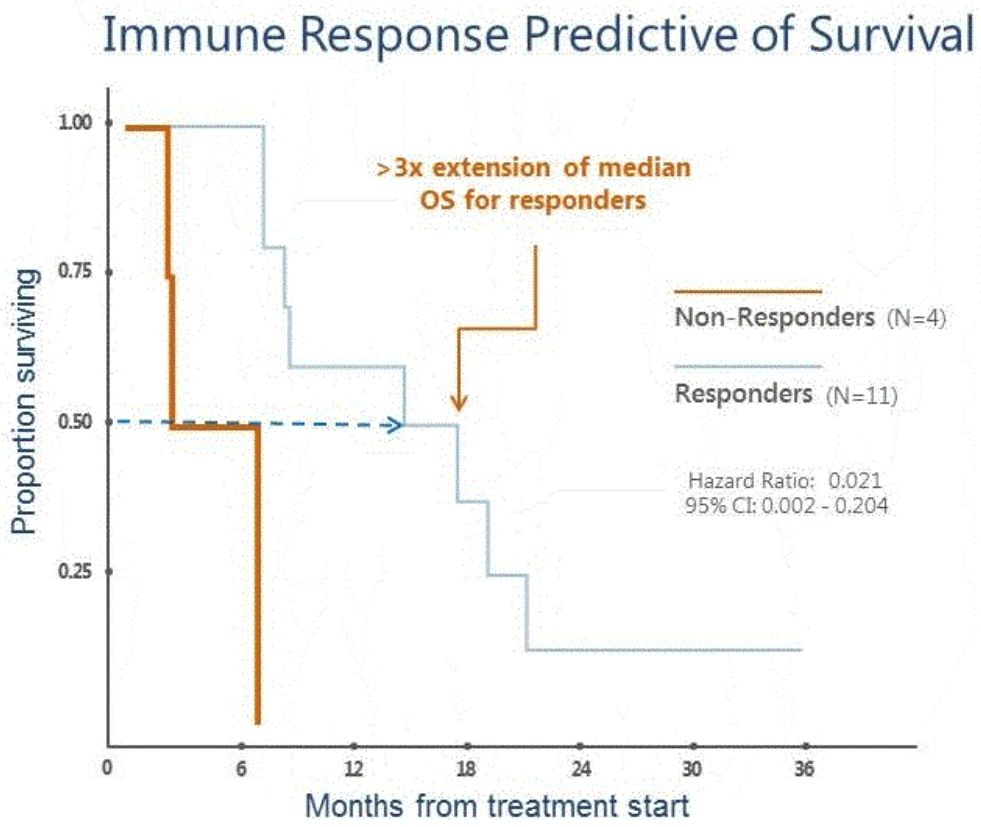


CD8 IFN- γ response. Samples from 15 patients collected for immune response at baseline and after at least one course of vaccination were available for analysis of the CD8 IFN- γ response. 20,000 purified patient CD8 T cells were stimulated with vaccine cells for 40h in ELI-spot plates and the frequency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

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. There were no objective tumor responses. The Kaplan Meier estimate of median time to progression was 1.4 months (95% CI: 1.3-2.7). The Kaplan-Meier estimate of median overall 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.

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-y) 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.



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-γ 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.

Other Cancers

We continue to evaluate other indications for our *ImPACT*® and *ComPACT*™ platform technologies. Specifically, using *ComPACT*™, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy for non-small cell lung cancer (HS-120). Our decision to further pursue these or any additional product candidates other than our two lead product candidates will be based in part upon available funding and partnering opportunities.

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.

We have retained Lonza Walkersville, Inc. a vendor, which has begun manufacturing of HS-110 to be used in our Phase 2 and potential Phase 3 clinical trials. We entered into an eight-year Manufacturing Services Agreement, dated October 20, 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 a certain minimum percentage of our annual global product requirements 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 product used in the inventor's Phase 1, and in our Phase 2 clinical trial and the HS-410 product used in our Phase 1/2clinical trial continues to be manufactured under cGMP (current good manufacturing practices). The vaccine cell line is grown in large quantities, dispensed into individual doses, frozen in liquid nitrogen, irradiated to render cell replication incompetent and quality tested in compliance with FDA guidelines. 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 remain metabolically active and secrete gp96-Ig. The batches of frozen, irradiated vaccine are stable for long periods of time, and are thawed immediately prior to administration to patients. Sufficient material to dose a subset of patients in the HS-110 clinical studies has already been produced, and preparations are underway to produce quantities required for trial completion and subsequent clinical trials. Sufficient material to complete the HS-410 clinical studies has already been produced.

Competition

The pharmaceutical industry and biologics industry are each highly competitive and characterized by a number of established large companies, and mid-sized 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 biotechnology company with cancer immunotherapy agents as lead product candidates, 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, radiotherapy, biologics and small molecule drugs. Not only do we compete with companies engaged in various cancer treatments including radiotherapy 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 with extensive facilities and equipment 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 and Company, Bristol-Myers Squibb Company, Merck & Co., Inc., Novartis AG, MedImmune, LLC (a wholly owned subsidiary of AstraZeneca plc), Johnson & Johnson, Pfizer Inc., MerckKGallogeneic and Sanofi-Aventis U.S. LLC, and more established biotechnology companies such as Genentech, Inc. (a member of the Roche Group), Amgen Inc., Celgene Corporation, Gilead Sciences, Inc., and competing cancer immunotherapy companies such as Kite Pharma, Inc., Juno Therapeutics, Inc., Bluebird Bio, Inc., Transgene SA, Valeant Pharmaceuticals International, Inc., NewLink Genetics Corporation, Agenus Inc., NovaRx Corporation, Aduro Biotech, Inc., Advaxis, Inc., ImmunoCellular Therapeutics, Ltd., Immunovaccine Inc., Oncothyreon Inc., Oxford BioMedica plc, Bavarian Nordic A/S, Celldex Therapeutics, Inc., Telesta Therapeutics Inc. and others, some of 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;
- 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 & Co. Inc., Genentech, Inc. (a member of the Roche Group); Bristol Myers Squibb Company; Transgene SA; Oxford BioMedica plc; NewLink Genetics Corporation; Celldex Therapeutics, Inc.; Pfizer Inc.; and Celgene Corporation.

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: nivolumab (Opdivo), pembrolizumab (Keytruda), Alimta (pemetrexed), Avastin (bevacizumab), Tarceva (erlotinib), Gemzar (gemcitabine), Carboplatin, Taxol (paclitaxel), Taxotere (docetaxel), and Vinorelbine. 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.

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. Immunotherapies are reported to cost in excess of $100,000 per year and we expect that our treatment will be less expensive.

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 exclusive 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*® and *ComPACT*™ therapy) and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States 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 our *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. 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. In July 2016, the Company and the University entered into an amendment replacing the milestone payment of $250,000 by the earlier of May 31, 2017 or approval of a BLA for the lung cancer vaccine with a payment of $500,000 upon approval of an NDA for a lung cancer vaccine covered by Patent Rights. 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 $500,000 upon approval of an NDA for the lung cancer vaccine or for a cancer vaccine other than lung cancer; and (v) royalties equal to a percentage (in the 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 agreed to postpone the payment due dates prior to February 2010 of this license agreement. All past patent costs have been fully paid.

In September 2014, we amended the license agreement in which the University of Miami agreed not to license the cell line to third parties while we are in good standing and in compliance of our patent license agreements with the University relating to our *ImPACT*® platform. A patent for "Modified Heat Shock Proteins-Antigenic Peptide Complex" if issued from the pending patent applications, would expire in 2019 (worldwide), not including any patent term adjustments or extensions.

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 run until all the patent-related rights licensed therein have expired, unless terminated earlier. In 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 titled "Cancer Treatment" and filed on May 21, 2010, and PCT/US2011/037327 titled "Cancer Treatment" and filed May 20, 2011, 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 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the "Cancer Treatment Portfolio"). A patent for "Cancer Treatment", if issued from the pending patent applications, would expire in 2031 (worldwide), not including any patent term adjustments or extensions.

- U.S. patent application serial number 61/033,425 titled "Allogeneic Cancer –Based Immunotherapy" and filed on March 3, 2008 and PCT application number PCT/US2009/001330 titled "Allogeneic Cancer –Based Immunotherapy" filed on March 3, 2009, 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 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the "Allogeneic Cancer –Based Immunotherapy Portfolio"). A patent for "Allogeneic Cancer –Based Immunotherapy", if issued from the pending applications, would expire in 2029 (worldwide), not including any patent term adjustments or extensions.

- U.S. patent application serial number 61/033,425 titled "Heat Shock Protein GP96 Vaccination and Methods of Using Same" filed on March 20, 2008 and PCT application number PCT/US2009/001727 titled "Heat Shock Protein GP96 Vaccination and Methods of Using Same" filed on March 19, 2009, 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 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the "Heat Shock Protein GP96 Vaccination Portfolio"). A patent for "Heat Shock Protein GP96 Vaccination and Methods of Using Same", if issued from the pending applications, would expire in 2029 (worldwide), not including any patent term adjustments or extensions.

- U.S. patent application serial number 61/116.971 titled "HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity" filed November 21, 2008 and PCT application number PCT/US2009/065500" titled "HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity" filed on November 23, 2009, 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 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the "HIV/SIV Vaccine Portfolio"). A patent for "HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity", if issued from the pending applications, would expire in 2029 (worldwide), not including any patent term adjustments or extensions.

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 of 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 percentage (in the 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 provides that the licensee will not have to pay more than the above-noted 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 our Preferred Stock), the University agreed to postpone the payment due dates prior to February 2010 for each of these four additional licenses.

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 used its best efforts to introduce, a licensed product in the commercial marketplace in the United States, European Union, 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 March 2014, our subsidiary, Heat Biologics I, Inc., entered into an additional exclusive license agreement with the University. The term of this license runs until all the patent-related rights licensed therein have expired, unless terminated earlier. In this exclusive license agreement, Heat Biologics I, Inc. obtained exclusive, worldwide rights to make, use or sell products covered under the University's interest in the following patent-related rights:

- U.S. Provisional Patent Application serial number 61/445,884 titled"Combined Cell Based Gp96-IG-SIV/HIV; Recombinant Gp120 Protein Vaccination For Protection From SIV/HIV" filed February 23, 2011 (the" '884 application"); PCT Application Serial No. PCT/US2012/26256 titled "Combined Cell Based Gp96-IG-SIV/HIV, Recombinant Gp120 Protein Vaccination For Protection From SIV/HIV" filed February 23, 2012 (the " '256 application"); and all U.S. patents and foreign patents and patent applications based on these applications; as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the '884 or '256 applications) of the foregoing, and any re-examinations or reissues of the foregoing (the "Combination HIV/SIV Vaccine Portfolio"). A patent for "Combined Cell Based Gp96-IG-SIV/HIV; Recombinant Gp120 Protein Vaccination For Protection From SIV/HIV", if issued from the pending applications, would expire in 2032 (worldwide), not including any patent term adjustments or extensions.

The patent rights in the Combination HIV/SIV Vaccine Portfolio are co-owned by the University and the National Institutes of Health (the "NIH"). Heat Biologics I, Inc. has only licensed the University's rights therein. The NIH's rights in this portfolio have not been licensed by Heat Biologics I, Inc. As consideration for the rights granted in this license agreement, the licensee is obligated to pay the University an upfront license fee, past patent costs, and royalties based on net sales on commercialized products covered by the patent-related rights set forth above. No annual payments are required under this license agreement. The licensee is obligated to make milestone payments under this license agreement as follows: $50,000 upon completion of a phase I clinical trial, $100,000 upon completion of a phase II trial, $100,000 upon completion of a phase III trial, and $100,000 upon acceptance of a BLA by the FDA or its foreign equivalent. Under this license agreement, the royalties are equal to a percentage (low single digits) of net sales of products covered by the patent-related rights. This 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. This license agreement also provides that the licensee will not have to pay more than the above sublicense fees or a royalty in the low-to-mid single digits if more than one license from the University is required to sell products covered by the licensed patent-related rights. The licensor has the right to terminate this license if the licensee has (i) not introduced, or at least use its best efforts to introduce, a licensed product in the commercial marketplace in the United States, European Union, or Japan by December 31, 2023; (ii) not otherwise exercised 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.

Upon an uncured material breach of an obligation under any one of the above six 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 above 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 the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the 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.

Under the above-described license agreements with the University, we have obtained exclusive rights to six different patent families. The six 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 eight (8) issued patents covering U.S., Australia, Canada, Japan and Europe (collectively validated in 28 countries), and one (1) pending U.S. application. 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 United States 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 patent granted in each of the United States, Canada, and Australia and one pending application each in Europe, Israel, and India. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

"Allogeneic 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 issued Australian patent, two issued U.S. patents, two issued European patents (validated into 19 countries), one issued Israeli patent and one pending application in each of Canada and India. 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 Canada and India. 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"

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. Within this family are one granted Australian patent, one granted South African patent, and one pending application in India. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

"Combined Cell-Based Gp96-Ig-SIV/HIV, Recombinant Gp120 Protein Vaccination for Protection From SIV/HIV"

This patent family relates to combination therapies for treating chronic viral infections including HIV. The combination therapy uses host cells that have been engineered to secrete a heat shock protein (gp96) to induce antiviral T cell responses and soluble viral antigens to induce antiviral antibody responses. Within this family are one issued patent in South Africa and one pending application each in Canada, India, South Korea, and the Philippines. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2032.

In July 2011, we exercised an option agreement with U.Mich and entered into a license agreement with U.Mich pursuant to which we are U.Mich's exclusive licensee and have the right to use, market, offer for sale, sell and/or sublicense materials and processes related to certain cancer cell lines. The term of the license is perpetual, unless terminated earlier by us or by U.Mich where U.Mich can only terminate for our material breach of this agreement. 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. 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 ATCC to evaluate, use, market, offer for sale, sell and/or sublicense materials and processes related to various different cell lines. In October 2013 and March 2014, this agreement was amended to add additional cell lines in exchange for additional fees. The agreement with ATCC provides for an evaluation term of 12 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 October 2013 amendment also increased the number of evaluation renewals to a total of five. The agreement with ATCC has a term of 40 years. We paid an evaluation fee and four renewal evaluation fees totaling $25,000, 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. In December 2015, we amended this agreement with ATCC to add additional cell lines in exchange for additional fees.

In September 2014, we entered into an exclusive license agreement for a multiple myeloma cell line with Professor Kenneth Nilsson in Sweden for the production, sale and use for immunotherapy, including the prevention or treatment of disease with substances, synthetic or biologic, that modulate the immune response and specifically exclude the use of the said cell line for discovery of any other therapeutics. The term of the license is perpetual, unless terminated earlier by us or by Professor Kenneth Nilsson where Profession Nilsson can only terminate for our material breach of this agreement. As consideration for the rights granted in the license agreement, we paid an up-front license fee of $5,000 and are obligated to pay an annual maintenance fee of $3,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to $30,000. In the license agreement, we agreed to pay royalties equal to a one-tenth of low single digit percentage of net sales of licensed products. In addition, we are obligated to make milestone payments of $12,000, $20,000 and $40,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial and $100,000 upon the first commercial sale of a licensed product and $200,000 upon annual net sales of $100,000,000 or more. The license agreement provides 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. There are no timelines to achieve the above milestones. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia.

In August 2015, we entered into an exclusive license agreement with Columbia University for an endometrial cancer cell line for the production, sale and use for all human healthcare applications. The term of the license is perpetual, unless terminated earlier by us or by Columbia University where Columbia University can only terminate for our material breach of this agreement. As consideration for the rights granted in the license agreement, we paid an up-front license fee of $7,500 and are obligated to pay an annual maintenance fee of $5,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to $50,000. In the license agreement, we agreed to pay royalties equal to a one-tenth of low single digit percentage of net sales of licensed products. In addition, we are obligated to make milestone payments of $25,000, $40,000 and $75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial and $200,000 upon the first commercial sale of a licensed product and $500,000 upon annual net sales of $100,000,000 or more. 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. There are no timelines to achieve the above milestones. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia.

Additionally, we have a pending international application and a pending U.S. application covering the *ComPACT*™ platform. If issued, it is expected that these applications will provide the Company protection to 2036, not including any patent term adjustments or extensions.

Together, our *ImPACT*®/*ComPACT*™ patent portfolio comprises over fifty issued patents and more than ten pending patent applications. These patents and applications cover the United States, Europe, and Japan as well as several other countries having commercially significant markets.

In October 2016, the Company's wholly-owned subsidiary, Zolovax, Inc., entered into an agreement with the University for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases. As consideration for the rights granted in this license agreement licensee is obligated to pay the University an upfront license fee and annual payments in the aggregate amount of $102,000 for the initial ten years and increasing thereafter. The licensee is obligated to pay royalties equal to a percentage (mid-single digits) of net sales of products covered by the patent-relayed rights, subject to reduction if additional licenses from third parties are required to commercialize licensed products. In addition, the licensee is obligated to make milestone payments in an aggregate amount of $1.45 million upon achievement of the following milestones: dosing of the first patients in each of the first Phase 1 clinical trial, Phase 2 clinical trial and Phase 3 clinical trial and upon receiving marketing approval by the first regulatory authority for the first product developed by licensee based upon the licensed patent rights. The license agreement provides that the licensee has the right to terminate the agreement upon sixty (60) days' notice and each party has the right to terminate the license agreement if the other party commits a material breach of an obligations under the license agreement and fails to cure such breach within thirty (30) days of receipt of notice. A material breach includes a failure to deliver a payment on time, failure to achieve a milestone schedule or failure to maintain required insurance. In addition, University has the right to terminate the agreement if licensee provide a false report to the University and continues in default for more than thirty (30) days after receiving notice of the default. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia. The preclinical studies using the licensed technology have been initiated and are progressing.

In June 2016, we entered into an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which we licensed certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by us. For a six month period, we received a monthly fee from Shattuck for supplying certain labor to Shattuck and reimbursement for certain supplies. In addition, we have signed a facility use agreement with Shattuck to use a portion of our office and lab space. Shattuck paid us an initial license fee of $50,000 and is obligated to pay us fees upon its receipt of sublicensing income, achievement of certain milestones and royalties upon sales of commercial products. In as much as the technology that we out-licensed is in the early stages of development and there is a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that we will derive any revenue from Shattuck.

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, (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 United States 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 United States. 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 $2,335,200, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding $110,370 per product and $569,200 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 12 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 nine 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 subject 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.

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.

On March 5, 2015, we were notified that the FDA granted FAST Track designation for HS-410 for the treatment of non-muscle invasive bladder cancer. We believe that this designation will expedite our development of HS-410.

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. Four Few biosimilars 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 are evaluated by the FDA through this approval process.

A reference biologic is granted 12 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) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 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. Products manufactured using the *ImPACT*® technology meet this threshold and therefore are considered biological drugs. Manufacture of*ImPACT*® products are subject to both cGTP and cGMP regulations for manufacturing quality. Marketing of these products in the United States will require FDA approval under the BLA pathway as discussed above.

Non-U.S. Regulation

Before our products can be marketed outside of the United States, 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; however, 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. There can be no assurance that the chosen regulatory strategy will secure regulatory approval 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 chemistry, manufacturing, clinical development and regulatory and quality assurance. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Our lung and bladder cancer trials have been registered on clinicaltrials.gov. 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. Research and development expenses were $9.3 million and $16.7 million during the years ended December 31, 2016 and 2015, respectively.

Employees

As of December 31, 2016, we had a total of 19 full-time employees. 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.

Item 1A. ***Risk Factors***

Investors should carefully consider the risks described below before deciding whether to invest in our securities. If any of the following risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this Annual Report on Form 10-K 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 clinical stage company and have had limited operations to date. We have yet to demonstrate our ability to overcome the risks frequently encountered in our industry and are still subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and products, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. Even if we generate revenue, there can be no assurance that we will be profitable. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks.

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

We are a clinical 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 preclinical development and successfully enroll patients in 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 completed any clinical trials other than the Phase 1 portion of our Phase 1/2 bladder cancer trial and has limited experience conducting and enrolling patients in clinical trials. Until recently, our operations have been limited primarily to organizing and staffing the Company, acquiring, developing and securing our proprietary technology and undertaking preclinical trials and preparing for our early 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.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern

Our operating losses, negative cash flows from operations and limited alternative sources of revenue raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements for the year ended December 31, 2016 do not include any adjustments that might result from the outcome of this uncertainty. If we cannot raise adequate capital on acceptable terms we will need to revise our business plans.

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

For the years ended December 31, 2016 and December 31, 2015, we incurred a net loss of $13.0 million and $21.1 million, respectively. We have an accumulated deficit of $57 million through December 31, 2016. We expect to 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 us obtaining regulatory approval for our product candidates and 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 any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale 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 expenses and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and conduct 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. As a result, we will need to generate significant revenues or raise additional financing 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 financing activities.

We will need to raise additional capital to operate our business and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.

During the year ended December 31, 2016, our operating activities used net cash of approximately $13.7 million and as of December 31, 2016 our cash and cash equivalents were approximately $7.8 million. During the year ended December 31, 2015, our operating activities used net cash of approximately $17.4 million and as of December 31, 2015 our cash and cash equivalents and short term investments were approximately $11.6 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2016, our accumulated deficit totaled approximately $57.0 million and as of December 31, 2015, our accumulated deficit totaled approximately $44.4 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any significant source in the near future until we or our potential partners successfully commercialize our products. Despite cost-saving measures that we implemented, we expect our expenses to increase if and when we initiate and conduct Phase 2 and 3 and other clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants.

We expect that our current cash and cash equivalents will allow us to complete the Phase 2 clinical trial for HS-410 and enroll additional patients in the Phase 2 clinical trial for HS-110; however, if the trial design or size were to change, we may need to raise money earlier than anticipated.

We will need to raise additional capital to fund our future operations and we cannot be certain that funding will be available on acceptable terms on a timely basis, or at alTo meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, which we expect will include sales of common stock through the FBR Sales Agreement, debt financings and/or funding from partnerships or collaborations. There can be no assurance that we will be able tomeet the requirements for use of the FBR Sales Agreement, especially in light of the fact that we are subject to the smaller reporting company requirements, or to complete any such transactions on acceptable terms or otherwise. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We currently have no product revenues and may not generate product 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 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. In addition, the technology that we out-licensed is in the early stages of development and there is a low likelihood of success for any such technology at that stage, therefore there can be no assurance that any products will be developed by such licensee or that we will derive any revenue from such licensee. For the foreseeable future, we will have to fund all of our operations from equity and debt offerings, cash on hand and grants. We believe that due to our current cash position and estimates of expenses, there is substantial doubt about our ability to continue as a going concern. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, preclinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect that we will seek additional sources of funding, such as additional financing or grant funding, and additional financing may not be available on favorable terms, if at all. Our ability to raise capital through the sale of equity may be limited by the various rules of the Securities and Exchange Commission and the Nasdaq Capital Market that place limits on the number of shares of stock that may be sold. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We are substantially dependent on the success of our product candidates and we cannot provide any assurance that any of our product candidates will be commercialized.

To date, our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our product candidates, HS-410 and HS-110, for which we are currently actively conducting Phase 2 clinical trials, respectively. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize these product candidates, which may never occur. Before commercializing either product candidate, we will require additional clinical trials and regulatory approvals for which there can be no guarantee that we will be successful. We currently generate no revenues from our product candidates, and we may never be able to develop or commercialize a marketable drug.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Our inability to locate and enroll a sufficient number of eligible patients in our clinical trials for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials. Our ability to enroll patients in trials is affected by many factors out of our control including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Risks Relating to our Business

If we do not obtain the necessary regulatory approvals in the United States 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 United States 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 BLA, demonstrating that the product candidate is safe, pure and potent, or effective for its intended use. This demonstration requires significant research including preclinical studies, as well as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

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

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any vaccines. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidates 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 preclinical and clinical testing. Although certain of our product candidates have commenced Phase 2 clinical trial, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical 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 preclinical testing. For example, the Phase 1 HS-410 clinical trial, as well as the interim data from the Phase 2 HS-410 clinical study, showed evidence of an immune response in NMIBC patients exposed to HS-410, however, the topline data from the Phase 2 clinical trial reported that there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. The Phase 2 clinical trial of HS-410 used doses and dosing regimens which had not previously been tested, and combinations with other immunotherapy agents. In addition, immune response is not an acceptable regulatory endpoint for approval, and the HS-410 Phase 1 trial involved a small sample size and was not randomized or blinded. 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 are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities. On February 2, 2016, we received notice from the FDA of a partial clinical hold on our Phase 2 HS-410 clinical trial despite the fact that we did not have a safety concern. The partial clinical hold came after we concluded that the cell line on which HS-410 is based had been previously misidentified. The partial clinical hold was lifted on February 10, 2016. However, if in the future we are delayed in addressing, or unable to address, any FDA concerns, we could be delayed, or prevented, from conducting our clinical trials.

Misidentification of cell lines could impact our clinical development and intellectual property rights.

Our product candidates are based on human cell lines produced by third parties and licensed by us. Cell line characterization and contamination is a known issue in biomedical research. For example, despite standard procedures to identify the origins and characteristics of our cell lines in early 2016 we discovered that the origin of the cell line used in HS-410 was misidentified. The misidentification resulted in the FDA placing our HS-410 Phase 2 clinical trial on partial clinical hold while the FDA reviewed certain updated documentation provided by us related to the misidentification. In the event we were to use a cell line in the future that is also misidentified, the clinical development of the product candidate utilizing the mischaracterized cell line could be materially and adversely affected, we could lose the right to use the cell line and our intellectual property rights relating to our development of product candidates based on that cell line could be materially and adversely affected. Although we have implemented certain additional procedures to properly identify our cell lines, we may not be able to detect that a cell line has been mischaracterized or mislabeled by a third party.

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 partially 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 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.

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

We have developed certain experience in the formulation, development and/or manufacturing of biologics but do not intend to establish our own manufacturing facilities. To date, the selection and initial replication of our biological cell lines used in our trials has been performed by individuals working at third party laboratories over which we have little process or quality control and therefore the process and replication could be subject to human error. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational products for our clinical trials are manufactured by our contractors under current good manufacturing practices, ("cGMPs") and we have entered into agreements with commercial-scale manufacturers for the production and supply of investigational product for additional Phase 2 and Phase 3 clinical trials as well as commercialization. We must also develop and validate a potency assay prior to submission of a license application. Such assays have traditionally proven difficult to develop for cell-based products and must be established prior to initiating any Phase 3 clinical trials. 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, we will be required 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. Accordingly, it may be necessary to evaluate the comparability of the HS-110 or HS-410 produced by the two different manufacturers at some point during the clinical development process.

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 likely 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 have in the past and may in the future 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 could also result in higher costs or deprive us of potential product revenues.

For each of our product candidates, we rely upon a single third party to manufacture and supply our drug substance. Any problems experienced by either our third party manufacturers or their vendors could result in a delay or interruption in the supply of our product candidate to us until the third party manufacturer or its vendor cures the problem or until we locate and qualify an alternative source of manufacturing and supply.

For each of our product candidates we currently rely on third party manufacturers to purchase from their third party vendors the materials necessary to produce our product candidates and manufacture our product candidates for our clinical studies. If either of our third party manufacturers were to experience any prolonged disruption for our manufacturing we could be forced to seek additional third party manufacturing contracts, thereby increasing our development costs and negatively impacting our timeliness and any commercialization costs.

For each of our ongoing clinical trials, we are administering our product candidates, in combination with other immunotherapy agents. Any problems obtaining the other immunotherapy agents could result in a delay or interruption in our clinical trials.

For our ongoing clinical trials of HS-110 we administer our product candidate in combination with another immunotherapy agent, nivolumab and for our clinical trial of HS-410 we administered our product candidate in combination with another immunotherapy agent, BCG. Therefore, our success will be dependent upon the continued use of these other immunotherapy agents. If any of the immunotherapy agents that are used in our clinical trials are unavailable while the trials are continuing, our timeliness and commercialization costs could be impacted. In addition, if any of these other immunotherapy agents are determined to have safety of efficacy problems, our clinical trials and commercialization efforts would be adversely affected.

Adverse effects resulting from other immunotherapy drugs or therapies could also negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product candidates.

There are many other companies that have developed or are currently trying to develop immunology vaccines for the treatment of cancer. If adverse effects were to result from any immunotherapy drugs or therapies being developed, manufactured and marketed by others it could be attributed to our products or immunotherapy protocols as a whole. In fact, in the past biologics have been associated with certain safety risks and other companies developing biologics have had patients in trials suffer from serious adverse events, including death. Any such attribution could negatively affect the perceptions by members of the health care community, including physicians, about the safety and effectiveness of our product candidates and the future of immunotherapy for the treatment of cancer. Our industry is susceptible to rapid technological changes and there can be no assurance that we will be able to match any new technological challenges presented by the adverse effects resulting from immunotherapy drugs or therapies developed, manufactured or marketed by others.

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 AEs 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.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have been granted fast track designation for HS-410 and may seek fast track designation for future product candidates. The FDA has broad discretion whether to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Moreover, we may not experience a faster development process, review or approval compared to conventional FDA procedures for HS-410, and the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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; and
- 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 preclinical 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 for 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, certain patents expire in 2019 and such protection does not prevent unauthorized use of such technology. In addition, our license for certain cell lines, such as our cell line used for HS-410, are subject to non-exclusive licenses and do not have patent protection. 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 with 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 upon 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 that 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 continue 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 certain dates, 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, 2017, 2018, 2019, 2020, and 2021 our minimum royalty obligations under our licensing agreements, required to be paid with the passage of time, are $90,374, $61,187, $30,000, $57,000 and $32,000, 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 therapies, 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 therapies. 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. In many countries, the government controls the pricing and profitability of prescription pharmaceuticals. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. In addition, recent changes in the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payers for health care treatment and services may take in response to any health care reform proposal or legislation. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainly remains regarding proposed significant reforms to the U.S. health care system.

We may not successfully effect our intended expansion

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

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

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

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

We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. Other than a $2,000,000 insurance policy on the life of Jeffrey Wolf, we do not have "key person" life insurance policies for any of our officers or advisors. The loss of the technical knowledge, 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 preclinical 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 additional 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.

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.

Uncertainty regarding health care reform and declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. 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. If the economic climate does not improve or continues to be uncertain, 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.

Risk Factors Specific to the Pelican Acquisition

If the conditions to the Acquisition are not met, the Acquisition will not occur.

Specified conditions must be satisfied or waived in order to complete the Acquisition, including, among others:

- participation in the Acquisition by the holders of at least 80% of the outstanding equity of Pelican on a fully diluted basis (which has subsequently been achieved);
- approval of the NASDAQ Capital Market of the issuance of the shares of Heat common stock to be issued to the Pelican stockholders in the Acquisition;
- the respective representations and warranties of Heat and Pelican shall be true and correct in all material respects as of the date of the Purchase Agreement and the closing;
- execution of contracts with respect to the CPRIT grant, subject to us committing to provide certain funding to Pelican by April 5, 2017;
- execution of the Stockholder's Agreement and Accredited Investor Questionnaire by each Participating Pelican Stockholder;
- performance or compliance in all material respects by us and Pelican with their respective covenants and obligations in the Purchase Agreement;
- Pelican shall have obtained any consents and waivers of approvals required in connection with the Acquisition; and
- no material adverse effect with respect to Heat or Pelican or its subsidiaries shall have occurred since the date of the Purchase Agreement.

These and other conditions are described in detail in the Purchase Agreement, which is included as an exhibit to this Annual Report on Form 10-K and incorporated by reference herein. Neither we nor Pelican can assure you that all of the conditions to the Acquisition will be satisfied. If the conditions to the Acquisition are not satisfied or waived, the Acquisition will not occur or will be delayed, and we and Pelican each may lose some or all of the intended benefits of the Acquisition.

Several of Pelican's directors have conflicts of interest that may influence them to support or approve the Acquisition without regard to your interests.

Jeffrey Wolf and Edward Smith serve on the board of directors of Heat and Pelican and are expected to continue to serve on the board of directors of Heat following the consummation of the Acquisition. Taylor Schreiber, M.D., Ph.D., serves as the Chairman of Heat's Scientific Advisory Board and serves on Pelican's board of directors. John Monahan, Ph.D. a director of Heat, is a member of the limited liability company that owns shares of common stock of Pelican. They each have a direct or indirect financial interest in both Pelican and our company.

The consideration to be received for the Pelican Shares is not adjustable based on the market price of our common stock, therefore the Acquisition consideration at the closing may have a greater or lesser value than it had at the time the Purchase Agreement was signed.

Included in the consideration to be paid to the Pelican stockholders for the Pelican common stock is a fixed number of shares of our common stock. Any changes in the market price of our common stock will not affect the number of shares holders of Pelican common stock will be entitled to receive upon consummation of the Acquisition. Therefore, if the market price of our common stock increases from the market price on the date of the Purchase Agreement prior to the consummation of the Acquisition, Pelican stockholders could receive Acquisition consideration with considerably more value. The Purchase Agreement does not include a price-based termination right.

In order to develop Pelican's product candidates and receive the grant funding awarded by CPRIT, we will have to devote significant resources to Pelican.

Neither we nor Pelican are expected to derive revenue from any source in the near future until they or their potential partners successfully commercialize products. The CPRIT Grant requires that Pelican provide matching funds for one half of the award amount in order for Pelican to receive the grant funding. In order to receive the full $15.2 million award over three years, Pelican must raise matching funds in the aggregate amount of $7,622,611. The grant award contract cannot be executed until the matching funds for the first fiscal year (June 2016 through May 2017) of the award ($910,231) are obtained. Once Pelican has received matching funds in the amount of $910,231, the grant award in the amount of $1,820,462 for the first contract fiscal year will be available to Pelican from CPRIT. For the second fiscal year (June 2017 through May 2018) of the award, Pelican must provide matching funds of $3,177,507 in order for CPRIT to provide $6,355,014 of grant funding. For the third fiscal year (June 2018 through May 2019) of the award Pelican must provide matching funds of $3,534,873 in order for CPRIT to provide $7,069,746 of grant funding. In addition, we have agreed to loan Pelican approximately $250,000 to pay Pelican's legal fees and expenses incurred in connection with the Acquisition. Our financial statements have been prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities, and the addition of Pelican's activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to its technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials, access the CPRIT award or obtain approval of our product candidates from the FDA and other regulatory authorities.

If Pelican is unable to hire additional qualified personnel, its ability to utilize the CPRIT grant will be forfeited

In order to access the CPRIT grant a majority of Pelican's employees must reside in Texas as well as its Chief Executive Officer and other executive officers. Pelican has identified qualified individuals and will have to negotiate agreements with each identified individual and will also need to hire such additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. Pelican will compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and there can be no assurance that the search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to Pelican's access to the CPRIT grant.

The Stock Consideration issuable to the Pelican Stockholders in the Acquisition will cause the Heat stockholders to experience dilution

The issuance of the Stock Consideration to the Pelican Stockholders will dilute an investor's equity ownership in our company by approximately 4.99% and, as a result, could have the effect of depressing the market price for our securities, especially if the anticipated benefits of the Acquisition do not materialize or otherwise result in increased stockholder value or revenue stream to the combined company.

Our stock price is expected to continue to be volatile, and the market price of our common stock may drop following the acquisition.

The market price of our common stock could be subject to significant fluctuations following the Acquisition. Moreover, Heat in general has experienced substantial volatility that has often been unrelated to our operating performance and the stock market in general has been subject to volatility often unrelated to any individual company performance. These broad market fluctuations may adversely affect the trading price of our common stock after the Acquisition. Set forth below is the range of the high and low sales prices of Heat's common stock for the years ended December 31, 2015 and 2016 on a quarterly basis.

	High	Low
YEAR ENDED DECEMBER 31, 2015		
First Quarter	$ 8.30	$ 3.99
Second Quarter	$ 8.35	$ 5.73
Third quarter	$ 6.58	$ 3.42
Fourth quarter	$ 4.50	$ 1.84
YEAR ENDED DECEMBER 31, 2016		
First Quarter	$ 4.32	$ 0.68
Second Quarter	$ 0.80	$ 0.46
Third Quarter	$ 1.81	$ 0.66
Fourth Quarter	$ 3.23	$ 0.70

During November 2016, daily trading volume has ranged from 250,000 shares to in excess of 20,000,000 shares. During December 2016 daily trading volume ranged from 600,000 shares to in excess of 13,000,000 shares. During January 2017, daily trading volume ranged from 250,000 shares to in excess of 8,000,000 shares.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation.

The combined company may not experience the anticipated strategic benefits of the Acquisition.

We believe that the Acquisition would provide certain strategic benefits that may not be realized by each of the companies if Pelican is not acquired by us. Specifically, we believe the Acquisition would provide certain strategic benefits which would enable us to accelerate our business plan through an increased access to capital in the public equity markets. The market price of our common stock may decline as a result of the Acquisition if the combined company does not achieve the perceived benefits of the Acquisition as rapidly or to the extent anticipated by us or Pelican or investors, financial or industry analysts. There can be no assurance that these anticipated benefits of the Acquisition will materialize or that if they materialize will result in increased stockholder value or revenue stream to the combined company.

We may be unable to successfully integrate the Pelican businesses with its current management and structure.

Our failure to successfully complete the integration of Pelican could have an adverse effect on our prospects, business activities, cash flow, financial condition, results of operations and stock price. Integration challenges may include the following:

- assimilating Pelican's technology and retaining personnel in Texas as required by the CPRIT grant award;
- estimating the capital, personnel and equipment required for Pelican based on the historical experience of management with the businesses they are familiar with;
- minimizing potential adverse effects on existing business relationships;
- successfully developing the new products and services; and
- coordinating our efforts throughout various distant localities such as Texas where Pelican is headquartered and must remain headquartered in order to access the CPRIT grant award.

Pelican has had limited operations to date.

Pelican is a start-up entity and has had limited operations to date. As a start-up entity, Pelican is subject to many of the risks common to such enterprises, including its ability to implement its business plan, market acceptance of its 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 its ability to generate revenues. There is no assurance that its activities will be successful or will result in any revenues or profit, and the likelihood of its success must be considered in light of the stage of its development. Even if it generates revenue, there can be no assurance that it will be profitable. In addition, no assurance can be given that it will be able to consummate its business strategy and plans, as described herein, or that financial, technological, market, or other limitations may force it to modify, alter, significantly delay, or significantly impede the implementation of such plans. Pelican has insufficient results for investors to use to identify historical trends or even to make quarter to quarter comparisons of its operating results. Pelican's revenue and income potential is unproven and its business model is continually evolving. Pelican is subject to the risks inherent to the operation of a new business enterprise, and there can be no assurance that Pelican will be able to successfully address these risks.

Pelican has a limited operating history upon which to evaluate its ability to commercialize its products

Pelican is a development-stage company and its success is dependent upon its ability to develop and commercialize its products and it has not demonstrated an ability to perform the functions necessary for the successful development and commercialization of any product candidates. The successful commercialization of any product candidates will require Pelican to perform a variety of functions, including:

- continuing to undertake preclinical development trials and initiating clinical trials;
- participating in regulatory approval processes and obtaining regulatory approvals;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Pelican's operations have been limited to organizing and staffing Pelican, acquiring, developing and securing its proprietary technology and undertaking preclinical studies of its product candidates. Pelican has yet to engage in any clinical trials and therefore the safety of its product candidates is uncertain.

Pelican has generated operating losses and experienced negative cash flows and it is uncertain whether it will achieve profitability.

For the year ended December 31, 2016, Pelican incurred a net loss of ($703,736). At December 31, 2016, Pelican had an accumulated deficit of ($3,042,685), a stockholder's deficit of ($990,299) and a working capital deficiency of ($553,471). Pelican will continue to incur operating losses until such time, if ever, as it is able to achieve sufficient levels of revenue from operations. Its ability to achieve profitability will depend on the market development and acceptance of its product offerings and its capacity to develop, introduce and sell its products to its targeted markets. There can be no assurance that Pelican 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.

It is expected that Pelican will experience negative cash flows for the foreseeable future as it funds its operating losses and capital expenditures. As a result, we may seek to raise additional funding in the future in order to obtain matching funds under the CPRIT Grant. We may not be able to raise additional funding on favorable terms or at all.

Pelican's independent auditor has expressed substantial doubt about its ability to continue as a going concern.

Pelican's consolidated financial statements as of December 31, 2016 have been prepared under the assumption that it will continue as a going concern for the next twelve months. Its independent auditor has issued a report that includes an explanatory paragraph referring to its recurring losses from operations and expressing substantial doubt in its ability to continue as a going concern without additional capital becoming available. Pelican's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. Pelican's consolidated financial statements as of December 31, 2016 did not include any adjustments that might result from the outcome of this uncertainty. If Pelican cannot continue as a viable entity, Heat and its other stockholders may lose some or all of their investment in Pelican.

Pelican's product candidates are in early stages of clinical trials

Because Pelican's product candidates are in early stages of development they will require extensive preclinical and clinical testing. Pelican's lead product has not yet entered clinical trials and cost, speed and ability to advance through clinical trials is uncertain. Pelican cannot predict with any certainty if or when it might submit a Biologics License Application (BLA) for regulatory approval for any of its product candidates or whether any such BLA will be accepted.

Pelican relies on licenses to use various technologies that are material to its business and if the agreements were to be terminated, it would halt its ability to market its products and technology, as well as have an immediate material adverse effect on its business, operating results and financial condition.

Pelican has licensing agreements with the University granting it the right to use certain critical intellectual property. The terms of the licensing agreements continue until the end of the life of the last patent to expire. If Pelican breaches the terms of these licensing agreements, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones such as use best efforts to introduce a licensed product in certain territories by 2020, the licensor has the right to terminate the license. If Pelican were to lose or otherwise be unable to maintain these licenses on acceptable terms, it would halt its ability to market its products and technology, which would have an immediate material adverse effect on its business, operating results and financial condition.

Pelican may be unable to generate sufficient revenues to meet the minimum royalties or developmental milestones required under its license agreements or to pay outstanding obligations.

For the year ending December 31, 2017 and thereafter Pelican's minimum royalty obligations (exclusive of any milestone payments) under its licensing agreements are $40,000 annually. No assurance can be given that Pelican 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 Pelican 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 Pelican were to lose or otherwise be unable to maintain these licenses, it would halt its ability to market its products and technology, which would have an immediate material adverse effect on its business, operating results and financial condition.

There is uncertainty as to market acceptance of Pelican's technology and products.

Pelican has conducted its own research into the markets for its products; however, because it will be a new entrant into the market, it cannot guarantee market acceptance of its products and have somewhat limited information on which to estimate anticipated level of sales. Pelican's products will require patients and doctors to adopt its technology. Pelican's industry is susceptible to rapid technological developments and there can be no assurance that it will be able to match any new technological advances. If it is unable to match the technological changes in the needs of its customers the demand for its products will be reduced.

Risks Related to Our Common Stock

Our failure to meet the continued listing requirements of the NASDAQ Capital Market could result in a de-listing of our common stock.

Our shares of common stock are currently listed on The NASDAQ Capital Market. If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, The NASDAQ Capital Market may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase its common stock when they wish to do so. On March 15, 2017, we received written notice from the Listing Qualifications Department of NASDAQ Stock Market LLC ("NASDAQ") notifying us that for the preceding 30 consecutive business days (January 31, 2017 through March 14, 2017), our common stock did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per share as required by NASDAQ Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of our common stock which will continue to trade on The NASDAQ Capital Market under the symbol "HTBX". In accordance with NASDAQ Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days, or until September 11, 2017, to regain compliance with NASDAQ Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case NASDAQ will notify us of our compliance and the matter will be closed. If, however, we do not achieve compliance with the Minimum Bid Price Requirement by September 11, 2017, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The NASDAQ Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify NASDAQ in writing of our intention to cure the deficiency during the second compliance period. The March 15, 2017 notice was the third notice we received from NASDAQ notifying us that we were not in compliance with continued listing requirements of The NASDAQ Capital Market No assurance can be given that we will be able to satisfy its continued listing requirements and maintain the listing of our common stock on The NASDAQ Capital Market. We intend to attempt to take actions to restore its compliance with NASDAQ's listing requirements, but we can provide no assurance that any action taken by us would result in our common stock meeting the NASDAQ listing requirements, or that any such action would stabilize the market price or improve the liquidity of our common stock.

On May 2, 2016, we received written notice from the Listing Qualifications Department of NASDAQ Stock Market LLC ("NASDAQ") notifying us that for the preceding 30 consecutive business days (March 18, 2016 through April 29, 2016), our common stock did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per share as required by NASDAQ Listing Rule 5550(a)(2). Compliance was achieved automatically and without further action when the closing bid price of our common stock was at or above $1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period

In addition, on February 22, 2016, we received a deficiency letter from the NASDAQ indicating that as of December 31, 2015 our stockholders' equity of $2,495,000 did not meet the $2,500,000 minimum required to maintain continued listing. Although the proceeds of our March 2016 offering satisfied the continued listing requirements of the NASDAQ with respect to stockholders' equity, there can be no assurance that we will continue to satisfy such requirements

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 (the "2009 Plan"). In 2014, we adopted a 2014 Stock Incentive Plan (the "2014 Plan") and in 2016 and 2015 we increased the number of shares of common stock that we have authority to grant under the 2014 Plan to a total of 3 million shares. As of December 31, 2016, awards for 2,430,012 shares of common stock have been granted under the 2009 Plan and the 2014 Plan and there were 2,351,230 shares of common stock remaining available for grant under these plans. In addition, as of December 31, 2016, we have 17,392 shares issuable upon exercise of warrants granted to third parties in connection with prior private placements of our equity securities and debt, 2,961,571 shares of common stock issuable upon exercise of warrants granted to third parties in connection with our recent public offering, and 125,000 shares of common stock issuable at $12.50 per share upon exercise of warrants issued to the underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

Our Third Amended and Restated Certificate of Incorporation authorizes the issuance of 50,000,000 shares of our common stock and 10,000,000 shares of Preferred Stock. In certain circumstances, the common stock and preferred stock, as well as the awards available for issuance under the 2009 and 2014 Plans, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of Preferred Stock and common stock. In addition, the issuance of Preferred Stock may be used as an "anti-takeover" device without further action on the part of our stockholders, and may adversely affect the holders of the common stock.

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

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

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

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

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

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

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

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

On March 28, 2017 we had 33,526,992 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders 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 stockholders 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 stockholders to lose part or all of their investment in our shares of common stock.

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

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

The trading in our stock has in the past and may continue to be very volatile.

Our stock price and the trading volume of our stock continues to be very volatile. As such, investors may find it difficult to obtain accurate stock price quotations and holders of our stock may be unable to resell their stock at desirable prices. Sales of substantial amounts of our common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short period of time. As a result, our stockholders could suffer losses or be unable to liquidate holdings.

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

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

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until warrant holders acquire shares of our common stock upon exercise of their warrants, the warrant holders will have no rights with respect to shares of our common stock issuable upon exercise of their warrants. Upon exercise of the warrants, the warrant holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The warrants issued in our recent public offering may not have any value.

Each warrant that we issued in our recent public offering will have an exercise price of $1.00 per share and will expire on the fifth anniversary of the original issuance date. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established market for the warrants issued in our recent public offering to purchase shares of our common stock being offered in this offering.

There is no established trading market for the warrants issued in our recent public offering and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

The shares of common stock offered under the FBR Sales Agreement may be sold in "at the market" offerings, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under the FBR Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.

Securities research analysts, including those affiliated with our underwriters, establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business or if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage following this offering, if no securities or industry analysts begin to cover us, the trading price for our stock and the trading volume could be adversely affected.

Our management team may invest or spend the proceeds of our prior offering in ways with which stockholders may not agree or in ways that may not yield a significant return.

Our management will have broad discretion over the use of proceeds from our March 2016 public offering, At-the-Market offering, and additional future financings. The net proceeds from the public offerings are to be used for general corporate purposes, which may include, among other things, increasing our working capital, funding research and development, clinical trials, vendor payables, potential regulatory submissions, hiring additional personnel and capital expenditures. Our management has considerable discretion in the application of the net proceeds, and stockholders will not have the opportunity to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our operating results or enhance the value of our common stock.

Our need for future financing may result in the issuance of additional securities that 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 expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms that may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing may dilute an investor's equity ownership and have the effect of depressing the market price for our securities. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

Facilities

Our executive offices are located at 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. On January 24, 2014, we entered into a five-year lease for 5,303 square feet of office and laboratory space for monthly rent of $10,341 exclusive of payments required for maintenance of common areas and utilities. On September 30, 2014, the lease was amended to expand the premises by an additional 676 square feet for a total of 5,979 square feet for a monthly rent of $11,638. We believe that such facilities are adequate for our current operations, and that there are spaces available sufficient for any future expansion requirements should the need arise.

Item 3. ***Legal Proceedings***

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities***

Our common stock has traded on the NASDAQ Capital Market under the symbol "HTBX" since July 29, 2013. Prior to that time, there was no public market for our common stock. The following table states the range of the high and low sales prices of our common stock for the year ended December 31, 2015 and the year ended December 31, 2016. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NASDAQ on March 28, 2017 was $1.03 per share. As of March 28, 2017, there were approximately 30 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

	High	Low
YEAR ENDED DECEMBER 31, 2015		
First Quarter	$ 8.30	$ 3.99
Second Quarter	$ 8.35	$ 5.73
Third quarter	$ 6.58	$ 3.42
Fourth quarter	$ 4.50	$ 1.84
YEAR ENDED DECEMBER 31, 2016		
First Quarter	$ 4.32	$ 0.68
Second Quarter	$ 0.80	$ 0.46
Third Quarter	$ 1.81	$ 0.66
Fourth Quarter	$ 3.23	$ 0.70

Dividend Policy

We have never paid any cash dividends on our common stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Delaware corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2016.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2009 Equity Incentive Plan	249,767	$2.68	222,477
2014 Equity Incentive Plan	886,986	$4.28	2,020,057
Equity compensation plans not approved by security holders	—	—	—
Total	1,136,753	$3.93	2,242,534

Subsequent to December 31, 2016, we issued Ann Rosar and Jeff Wolf options exercisable for 70,000 and 125,000 shares of common stock, respectively, vesting pro rata on a monthly basis over four (4) years as part of their 2016 bonus. We also issued Ann Rosar and Jeff Wolf 70,000 and 125,000 Restricted Stock Units which vest 25% on grant date, and 25% on each anniversary of grant date, thereafter. As part of his employment agreement, we issued Jeff Hutchins 200,000 stock options, vesting pro rata on a monthly basis over four (4) years at an exercise price of $0.88 per share.

Recent Sales of Unregistered Securities

All sales of unregistered securities have been previously reported.

Purchase of Equity Securities

We have not purchased any of our equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. ***Selected Financial Data***

Not applicable because we are a smaller reporting company.

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion of our financial condition and results of operations and comprehensive loss should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2016 found in this report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "anticipate," "believe," "intends," or similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.

Company Overview

We are an immuno-oncology company developing novel therapies designed to activate a patient's immune system against cancer utilizing an engineered form of gp96. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT*® (Immune Pan-Antigen Cytotoxic Therapy) and *ComPACT*™ (Combination Pan-Antigen Cytotoxic Therapy), form the basis of our product candidates. Our platform technologies address two synergistic mechanisms of action: activation and proliferation of CD8+ T cells, or "killer" T cells; and T cell co-stimulation. We believe the use of these technologies in combination with other immunotherapies has the potential to dramatically improve patient outcomes.

Using our *ImPACT*® platform technology, we have developed product candidates that consist of live, genetically-modified, irradiated human cancer cells which secrete a broad spectrum of tumor-associated antigens ("TAAs") together with a potent immune response stimulator called gp96. The secreted antigen-gp96/TAA complexes are designed to activate a patient's immune system to recognize and kill cancer cells that express the TAAs included in the product candidates, which we have selected to address the most prevalent TAAs present in the "tumor signature" of a specific cancer.

Our *ComPACT*™ platform technology enables us to combine a pan-antigen T cell activating vaccine and a T cell co-stimulator in a single product, offering the potential benefits of combination immunotherapy without the need for multiple independent biologic products. Using *ComPACT*™, we have engineered new product candidates that incorporate various ligand fusion proteins targeting co-stimulatory receptors (OX40, ICOS, 4-1BB, TL1A, etc.) into the gp96-Ig expression vector, resulting in a single product candidate that includes both a pan-antigen T cell priming vaccine and a T cell co-stimulator.

Using our platform technologies, we produce product candidates from allogeneic cell lines selected to express the broadest array of commonly shared tumor antigens for a specified type of cancer. Unlike autologous or "personalized" therapeutic vaccine approaches that require the extraction of blood or tumor tissue from each patient and the creation of an individualized treatment, our product candidates are fully allogeneic and do not require extraction of individual patient's material or custom manufacturing. As a result, our product candidates can be mass-produced and readily available for immediate patient use. Because each patient receives the same treatment, we believe that our immunotherapy approach offers logistical, manufacturing and other cost benefits compared to patient-specific or precision medicine approaches.

Our wholly-owned subsidiary, Zolovax, Inc. ("Zolovax"), is developing therapeutic and preventative vaccines to treat infectious diseases based on our gp96 vaccine technology, with a current focus on the development of a Zika vaccine in collaboration with the University of Miami. Other infectious diseases of interest include HIV, West Nile virus, Dengue and yellow fever.

Using our *ImPACT*® platform technology, we have developed two product candidates: HS-110 (viagenpumatucel-L) as a potential treatment for patients with non-small cell lung cancer ("NSCLC"), currently in combination with an anti-PD-1 checkpoint inhibitor, and HS-410 (vesigenurtacel-L) as a product candidate to treat non-muscle invasive bladder cancer ("NMIBC"). To date, we have administered in excess of 1,000 doses of HS-410 and HS-110 collectively in almost 200 patients, generating a favorable safety profile and low toxicities. We are currently conducting a Phase 2 trial of HS-110, in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb PD-1 checkpoint inhibitor, to treat patients with NSCLC and a Phase 2 trial of HS-410 in patients with NMIBC.

We are devoting substantially all of our resources to developing HS-110 and HS-410 including conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue from product sales since our inception. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- complete the ongoing clinical trials of our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- seek to obtain regulatory approvals for our product candidates;
- continue our research and development efforts;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- operate as a public company.

We commenced active operations in June 2008. Our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates and undertaking preclinical and clinical studies of our most advanced product candidates. To date, we have not generated any significant revenues and have primarily financed our operations with net proceeds from the private placement of our preferred stock, our July 2013 initial public offering in which we received net proceeds of $24.3 million, our March 2015 public offering in which we received net proceeds of $11.1 million, our March 2016 public offering of 9,100,000 shares of our common stock and warrants to purchase up to an aggregate of 6,825,000 shares of our common stock at a combined price of $0.75 per share for net proceeds of $6.1 million and, as of December 31,2016, an additional $3.9 million from the exercise of 3,863,429 warrants. In addition, we have received $6.8 million of net proceeds from sales through the At Market Issuance Sales Agreement (the "FBR Sales Agreement") with FBR Capital Markets & Co. through December 31, 2016, $7.5 million received from our debt facility which has been paid back in full, and our recent public offering that was completed on March 28, 2017 of 5,000,000 shares of our common stock and an additional issuance of 750,000 shares of our common stock on March 30, 2017 in connection with the underwriter's exercise of their over-allotment option (the "Offering") at a price to the public of $0.80 per share for gross proceeds of $4.6 million and estimated net proceeds of approximately $4.1 million after deducting underwriting discounts and commissions and other estimated offering expenses. Our consolidated financial statements for the years ended December 31, 2016 and 2015 have been prepared on a going concern basis. As of December 31, 2016, we had an accumulated deficit of $57.0 million. We had net losses of $12.6 million and $21.1 million for the years ended December 31, 2016 and 2015, respectively.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Accordingly, there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so.

HS-110 (viagenpumatucel-L) – Non-Small Cell Lung Cancer

HS-110 (viagenpumatucel-L) is a biologic product candidate comprising a cancer cell line that has been genetically modified using our *ImPACT*® technology platform to secrete a wide range of cancer-associated antigens related to lung cancer bound to gp96 proteins. We believe that HS-110 has the potential to activate a T cell-mediated pan-antigen immune response that could be an effective treatment for patients with NSCLC.

We are conducting a Phase 2 clinical trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, to treat patients with NSCLC. The trial is structured as a Phase 1b/Phase 2 with pre-specified thresholds in place to expand the trial to a full Phase 2. The multicenter, open-label trial is expected to initially enroll 18 patients evaluable for baseline biopsy and is designed to accommodate cohort expansion in Phase 2 up to 30 patients per arm (approximately 60 patients). The purpose of the trial is to evaluate the safety and efficacy of HS-110 in combination with nivolumab, an FDA approved anti-PD-1 checkpoint inhibitor, in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival. Trial enrollment is currently ongoing.

On March 21, 2017, we reported positive interim results for the Phase 2 trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. ELISPOT results suggest that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients. Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions. No tumor reductions were observed in patients that did not mount an immune response to HS-110. The timing of immune response to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained. Furthermore, to-date 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort. Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported by Teng et al, Cancer Research 75(11) June 1, 2015 for existing data on nivolumab alone.

On March 13, 2017, we issued a press release announcing that we achieved the safety and efficacy endpoints for the Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo®), for the treatment of NSCLC and that the trial met the expansion criteria to advance into a Phase 2. Five out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of TIL at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point. The Data Monitoring Committee concluded that the positive safety profile, mechanistic evidence and encouraging signs of synergistic efficacy warranted expansion to a Phase 2 trial.

On December 6, 2016, we reported that 1-year results from the first eight trial patients showed that the HS-110/nivolumab combination was well tolerated with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in the HS-110/nivolumab combination compared to existing data on single agent nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy ("immune responders") had longer overall survival and better objective response rate than the non-immune responders, even though they had the same baseline immune function. Immune responders in the study saw a 50% objective response rate while non-immune responders saw a 0% objective response rate. Moreover, the immune responders had a better median overall survival than non-immune responders. The 1-year overall survival was 50% for the responders and 25% for the non-responders. Finally, immune responders also saw a better median overall survival at 12.7 months, than non-immune responders, who saw a median overall survival of 7.1 months. Researchers concluded that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors.

Heat also conducted a Phase 2 randomized, controlled trial using HS-110 in combination with cyclophosphamide versus chemotherapy alone in third-line and fourth-line NSCLC patients. This trial, which enrolled 66 of 123 patients, was discontinued in 2015 to allow Heat to instead focus on combinations with checkpoint inhibitors. Data from the Phase 2trial continues to accrue and will be reported in 2017. The trial was structured as a multicenter randomized study to evaluate the immune response, safety and efficacy endpoints of HS-110 when administered weekly for 12 weeks in combination with low-dose cyclophosphamide in an induction period followed by monotherapy HS-110 every nine weeks during maintenance for up to one year or until discontinuation from study treatment, whichever occurred first. Patients randomized to the comparator arm were treated with one chemotherapy regimen until progression. Blood samples were taken to evaluate the immune response and their correlation to overall survival, and where considered appropriate by the investigator, patients are invited to consent for pre- and post-treatment biopsies for exploratory biomarker analysis. The primary endpoint was overall survival; secondary endpoints follow objective responses and immune response.

HS-410 (vesigenurtacel-L) –Bladder Cancer

HS-410 (vesigenurtacel-L) is a biologic product candidate comprising a cancer cell line genetically modified using our*ImPACT*® technology platform to secrete a wide range of cancer antigens related to bladder cancer bound to gp96 molecules. We believe that HS-410 has the potential to activate a T cell mediated pan-antigen immune response that could be an effective treatment for patients with NMIBC.

We are currently conducting a Phase 2 trial evaluating HS-410 either alone or in combination with intravesical standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of high-risk NMIBC. Our Phase 2 trial will examine safety, tolerability, immune response and preliminary clinical activity of HS-410. The primary endpoint is one-year disease free survival.

On November 30, 2016, we announced that we presented topline data from the 94-patient Phase 2 trial at the Society of Urology Annual Meeting in San Antonio, Texas. Researchers reported that there were encouraging signs of anti-tumor activity as HS-410 generated a robust antigen-specific immune response to multiple tumor-associated peptides in treated patients, while there were no immune responses of this type in the placebo. However, these responses did not translate into clinical outcomes, and there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. To better assess the durability of the positive immunological responses, and in keeping with clinical trial guidance recently issued by International Bladder Cancer Group recommending a 2-year study duration for NMIBC trials, we will continue to monitor all patients enrolled in the study for an additional 12 months. At that time, we will make a final determination on whether to progress our bladder program into a Phase 3 trial.

Additional Indications

We continue to evaluate other potential indications for our*ImPACT*® and *ComPACT*™ platform technologies. Specifically, using *ComPACT*™, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy for non-small cell lung cancer (HS-120). Our decision to further pursue these product candidates or any additional product candidates other than our two lead product candidates will be based in part upon available funding and partnering opportunities.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

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

The notes to our audited consolidated financial statements contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

- Stock-based compensation;
- Research and development costs, including clinical and regulatory cost; and
- Recent accounting pronouncements.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. We apply the Black-Scholes-Merton option pricing model to determine the fair value of our stock options and restricted stock awards. Inherent in this model are assumptions related to expected stock-price volatility, expected option life, risk-free interest rate and dividend yield. We do not have sufficient history to estimate the volatility of our common stock, therefore we have elected to utilize a peer group of similar publicly traded companies for which the historical information is available. We estimate the expected life of our options using the simplified method. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those stock options expected to vest over the service period.

Research and Development Costs

We expense research and development costs associated with developmental products not yet approved by the FDA as well as costs associated with bringing our developmental products into advanced phase clinical trials as incurred. These costs consist primarily of pre-manufacturing and manufacturing drug costs, clinical trial execution, investigator payments, license fees, salaries, stock-based compensation and related personnel costs. Other costs include fees paid to consultants and outside service providers related to the development of our product candidates, and other expenses relating to the design, development, and testing and enhancement of our product candidates.

Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-01, *Business Combinations (Topic 805)* to clarify the definition of a business, which is fundamental in the determination of whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses combinations. The updated guidance requires that in order to be considered a business the integrated set of assets and activities acquired must include, at a minimum, an input and process that contribute to the ability to create output. If substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar assets, it is not considered a business, and therefore would not be considered a business combination. The update is effective for fiscal years beginning after December 15, 2018, and interim periods with fiscal years beginning after December 15, 2019. We are currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)—Restricted Cash*. ASU 2016-18 requires the statement of cash flows to be a reconciliation between beginning and ending cash balances inclusive of restricted cash balances. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and is to be applied using a retrospective transition method to each period presented. We do not anticipate ASU 2016-18 to have a material impact to our consolidated financial statements.

In August 2016 the FASB issued ASU No. 2016-15, *Statement of Cash Flows* (Topic 230). The guidance is intended to reduce diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The effective date for the standard for public entities is for fiscal years beginning after December 15, 2017. Early adoption is permitted, provided all amendments are adopted in the same period. The guidance requires application using a retrospective transition method. We do not anticipate ASU 2016-15 to have a material impact to our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09,*Compensation-Stock Compensation* (Topic 718): *Improvements to Employee Share-Based Payment Accounting (ASU 2016-09).* ASU 2016-09 provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax benefit or expense in the reporting period in which they occur (previously such amounts were recognized in additional paid-in capital); 2) excess tax benefits will be classified as an operating activity in the statement of cash flows; and 3) the option to elect to estimate forfeitures or account for them when they occur. ASU 2016-09 is effective beginning in the first quarter of 2017. Upon adoption of ASU 2016-09, we plan to account for forfeitures as incurred and we expect this adoption along with the retrospective impact on its classification of cash flows between operating and financing activities to be immaterial. We believe the impact of recording excess tax benefits in income taxes in our consolidated statement of earnings to be immaterial. The extent of impact to our consolidated financial statements is dependent upon our future stock price in relation to the fair value of awards on grant date and our future grants of stock-based compensation.

In February 2016, the FASB issued ASU 2016-02,*Leases (Topic 842)*, requiring lessees to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and (2) a right-of-use ("ROU") asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The update is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. We currently anticipate that upon adoption of the new standard, ROU assets and lease liabilities will be recognized in amounts that will be immaterial to the consolidated balance sheets.

In January 2016, the FASB issued ASU No. 2016-01,*Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01).* ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We do not expect the adoption of this guidance will have a material impact on our consolidated financial statements or related footnote disclosures.

In April 2015, the FASB issued ASU No. 2015-03,*Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03)* ASU 2015-03 revises Subtopic 835-30 to require that debt issuance costs be reported in the balance sheet as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e., an asset) on the balance sheet. The ASU provides examples illustrating the balance sheet presentation of notes net of their related discounts and debt issuance costs. Further, the amendments require the amortization of debt issuance costs to be reported as interest expense. Similarly, debt issuance costs and any discount or premium are considered in the aggregate when determining the effective interest rate on the debt. The amendments are effective for public business entities for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The adoption of ASU 2015-03 on January 1, 2016 resulted in the reclassification of $22,707 from non-current assets to an offset to long-term debt as of December 31, 2015. There was no debt at December 31, 2016.

In August 2014, FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40): *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). The amendments in ASU 2014-15 are intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual periods ending after December 15, 2016 with early adoption permitted. The Company adopted this standard in 2016. The impact of the adoption of the standard is included in Note 2 to our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09,*Revenue from Contracts with Customers (ASU 2014-09),* which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. With the deferral, the new standard is effective for the Company on January 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. Due to limited sales, we have evaluated our contracts and have concluded that the impact of adopting the standard will have no material impact on our consolidated financial statements and related disclosures.

RESULTS OF OPERATIONS

Year Ended December 31, 2016 and 2015

Revenues

For the year ended December 31, 2016, we recognized $341,643 in research funding revenue pursuant to our exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which Shattuck acquired the rights to take over the research and development of certain preclinical assets. This revenue was for research and development services, which include labor and supplies, provided to Shattuck. There was no revenue for the year ended December 31, 2015. Prior to 2015, revenues were comprised of grant awards. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.

Operating Expenses

Total operating expenses for the year ended December 31, 2016 decreased 36% to $13.4 million compared to $21.0 million for the year ended December 31, 2015. Operating expenses are primarily comprised of research and development and general and administrative expenses. For the year ended December 31, 2016, research and development expenses were $9.3 million and general and administrative expenses were $4.1 million as compared to research and development expenses of $16.7 million and general and administrative expenses of approximately $4.3 million for the year ended December 31, 2015. For the year ended December 31, 2016, research and development expenses represented approximately 69% of operating expenses and general and administrative expenses represented approximately 31% of operating expenses. For the year ended December 31, 2015, research and development expenses represented approximately 79% of operating expenses and general and administrative expenses represented approximately 21% of operating expenses.

Research and development expense

Research and development expenses decreased by 44% to $9.3 million for the year ended December 31, 2016 compared to $16.7 million for the year ended December 31, 2015 as we have focused our resources primarily on our two NMIBC and NSCLC trials. The $7.4 million decrease consists of the following:

- $6.4 million decrease in clinical program expenses of which approximately $5.1 million of the decrease is related to HS-110 and approximately $1.8 million of the decrease is related to HS-410 due to reductions in Chemistry Manufacturing and Control ("CMC") activities and trial enrollment costs, offset by a $0.3 million increase in CMC expenses for *ComPACT*™ and $0.2 million increase for lab supplies and other costs;
- $1.0 million decrease in unallocated expenses such as professional and consulting fees, personnel-related expenses, and travel and other costs due to our cost saving program implemented during the year.

The following table sets forth our research and development expenses related to our programs for the years ended December 31, 2016 and 2015.

	Year ended December 31,	
	2016	2015
Programs	(in thousands)	
HS-410	$ 3,073	$ 4,845
HS-110	1,491	6,658
HS-120	319	—
Other programs	663	421
Unallocated research and development expenses	3,785	4,742
Total research and development expenses	$ 9,331	$ 16,666

These decreases were offset by increased lab supplies and other costs of approximately $0.3 million associated with the Shattuck agreement.

General and administrative expense

General and administrative expense decreased approximately 5% to $4.1 million for the year ended December 31, 2016 compared to $4.3 million for the year ended December 31, 2015. The $0.2 million decrease was a result of a $0.2 million savings in personnel-related costs from the separation of two of our former executive officers and a reduction of approximately $0.2 million in professional fees offset by a $0.2 million increase in public company expenses including board related fees and public relations expense.

Interest income

Interest income decreased for the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease is due to the Company's decreased investment balance during the year ended December 31, 2016.

Other income

Other income was $0.7 million for the year ended December 31, 2016 as compared to $0.2 million for the year ended December 31, 2015. Other income is primarily related to the R&D Tax Incentive for expenses associated with clinical trial activities conducted in Australia.

Interest expense

Interest expense for the year ended December 31, 2016 was $0.6 million compared to $0.4 million for the year ended December 31, 2015, all of which is attributable to the Square 1 Bank loans. As of December 31, 2016, the loans had been repaid in total.

Net loss attributable to Heat Biologics, Inc.

We had a net loss attributable to Heat Biologics, Inc. of $12.6 million, or ($0.71) per basic and diluted share for the year ended December 31, 2016 compared to a net loss of $20.3 million, or ($2.53) per basic and diluted share for the year ended December 31, 2015.

BALANCE SHEET AS OF DECEMBER 31, 2016 AND 2015

Investments, held to maturity (net)

Investments held to maturity (net) were $0 as of December 31, 2016 compared to $6.7 million as of December 31, 2015 as the Company moved its short-term investments into money market accounts.

Prepaid Expenses

Prepaid expenses decreased $0.5 million as of December 31, 2016 compared to December 31, 2015 largely due to the amortization of upfront payments made to our clinical trial vendors. Prepaid expenses consist of insurance, subscription software, and other upfront payments to vendors.

Accounts Payable

Accounts payable was $0.3 million as of December 31, 2016 compared to $2.0 million as of December 31, 2015. This decrease of $1.7 million was primarily related to the cost-savings plan and focused corporate strategy we implemented on April 1, 2016.

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities were $1.3 million as of December 31, 2016 compared to $1.8 million as of December 31, 2015. The decrease of $0.5 million was primarily related to decreased clinical trial activity.

Other Long term Liabilities

Long term liabilities were $0.5 million as of December 31, 2016 compared to $0.2 million as of December 31, 2015. The increase of $0.3 million was primarily related to the percent of investigator site fees that are held back until the clinical study is complete.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

To date, we have not generated any significant revenues. Since our inception in June 2008, we have financed our operations principally through private placements, our July 2013 initial public offering, our March 2015 public offering, our March 2016 public offering, the FBR Sales Agreement, and debt commitments. In connection with our July 2013 initial public offering, we sold 2,700,000 (including the 200,000 over-allotment option shares) shares of our common stock at a price of $10.00 per share. Aggregate gross proceeds from the IPO were $27.0 million and net proceeds received after underwriting commissions and offering expenses of $2.7 million were $24.3 million. In March 2015, we sold 1,640,000 shares of the Company's common stock, and 246,000 additional shares of the common stock to cover over-allotments at an offering price of $6.50 per share. The total gross proceeds from the March 2015 offering and subsequent over-allotment option was $12.3 million, before underwriting discounts, commissions and other offering expenses payable by us. The net proceeds to us were approximately $11.1 million. From our March 2016 public offering we have received net proceeds of approximately $6.1 million and an additional $3.9 million from the exercise of 3,863,429 warrants as of December 31, 2016. We have received net proceeds of approximately $6.8 million, after FBR's commission of $0.2 million and other expenses of $0.1 million, from sales of our common stock through the FBR Sales Agreement.

In August 2014, we entered into a secured loan with Square 1 Bank ("Loan"). The Loan provided us with a term loan in the aggregate principal amount not to exceed $7.5 million to be used to supplement working capital. In December 2016, we paid back the loan in full.

We believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated cash needs for the next twelve months. We intend to spend substantial amounts on research and development and clinical and regulatory activities, including product development, regulatory and compliance, clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. If we consummate the Pelican Acquisition, we will be required to devote additional funds to Pelican. The CPRIT Grant requires that Pelican provide matching funds for one half of the award amount in order for Pelican to receive the grant funding. In order to receive the full $15.2 million award over three years, Pelican must raise matching funds in the aggregate amount of $7,622,611. The grant award contract cannot be executed until the matching funds for the first fiscal year (June 2016 through May 2017) of the award ($910,231) are obtained. Once Pelican has received matching funds in the amount of $910,231, the grant award in the amount of $1,820,462 for the first contract fiscal year will be available to Pelican from CPRIT. For the second fiscal year (June 2017 through May 2018) of the award, Pelican must provide matching funds of $3,177,507 in order for CPRIT to provide $6,355,014 of grant funding. For the third fiscal year (June 2018 through May 2019) of the award Pelican must provide matching funds of $3,534,873 in order for CPRIT to provide $7,069,746 of grant funding. In addition, we have agreed to loan Pelican approximately $250,000 to pay Pelican's legal fees and expenses incurred in connection with the Acquisition and to pay an additional $250,000 of Pelican liabilities.

To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, which we expect will include sales of common stock through the FBR Sales Agreement, debt financings and/or funding from partnerships or collaborations. There can be no assurance that we will be able to meet the requirements for use of the FBR Sales Agreement, especially in light of the fact that we are subject to the smaller reporting company requirements, or to complete any such transactions on acceptable terms or otherwise. Even if we meet the requirements to use the FBR Sales Agreemen, we may not raise enough money through the use of the FBR Sales Agreement and may sell securities through any one of the methods mentioned above at various times or at the same time as we use the FBR Sales Agreement. If we are unable to obtain the necessary capital, we will scale back our operations, license or sell our assets, seek to be acquired by another entity and/or cease operations. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates and in April 2016, we implemented a cost-savings plan and focused corporate strategy involving reductions in headcount and reduction in cost structure to scale the organization appropriately for its current goals. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to direct our resources primarily to enable the completion of our Phase 2 clinical trial of HS-410 for the treatment of non-muscle invasive bladder cancer (NMIBC) and to advance the Phase 2 trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC). As of December 31, 2016, we had $7.8 million in cash and cash equivalents.

Cash flows

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The significant decrease in cash used in operating activities for the year ended December 31, 2016 compared to the year ended December 31, 2015 was due to a decrease in clinical and regulatory expenses as we direct our resources primarily to enable the completion of our Phase 2 clinical trial of HS-410 for the treatment of non-muscle invasive bladder cancer (NMIBC) and to advance the Phase 1b/2 trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCLC. Additionally, there was a decrease in other operational costs primarily associated with decreases in headcount and/or consultants in all departments.

Investing activities. Cash provided by investing activities during the years ended December 31, 2016 and 2015 included the proceeds from maturities of various short-term investments offset by purchases of these investments and purchases of property and equipment. During the year ended December 31, 2016 the Company sold its remaining short term investments and no longer holds debt securities.

Financing activities. Cash provided by financing activities during the year ended December 31, 2016 was from the March 2016 public offering and subsequent exercise of 3,863,429 warrants which generated net proceeds of approximately $10.0 million (after deduction of offering expenses), as well as approximately $6.8 million in net proceeds (after deduction of offering expense) from sales through the At The Market Issuance Sales Agreement during 2016. These inflows of cash were offset by payments of $6.8 million to Square 1 Bank to pay off our outstanding loan in total. Cash provided by financing activities during the year ended December 31, 2015 was primarily from the March 2015 public offering and exercise of the over-allotment option which generated net proceeds of approximately $11.1 million (after deduction of offering expenses) as well as $4.5 million in proceeds from Tranche 3 and Tranche 4 of the Loan.

OFF-BALANCE SHEET ARRANGEMENTS

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

Current and Future Financing Needs

We have incurred an accumulated deficit of $57.0 million through December 31, 2016. 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.

We believe that our existing cash and short-term investments will not be sufficient to fund our current operating plan and capital expenditure requirements for the next 12 months. We intend to meet our financing needs through multiple alternatives, including, but not limited to, additional equity financings, debt financings and/or funding from partnerships or collaborations.

However, the actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- 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;
- the costs and timing of regulatory approvals; and
- profitability of our clinical laboratory diagnostic and microbiology services business.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity 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, and it is uncertain whether 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, including accessing the CPRIT grant if the Pelican Acquisition is consummated. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

License and Contractual Agreement Obligations

Below is a table of our contractual obligations for the years 2017 through 2021 as of December 31, 2016 (in thousands).

	2017	2018	2019	2020	2021	Total
License agreements	$ 91	$ 61	$ 30	$ 57	$ 32	$ 271
Lease agreements	225	232	197	—	—	654
Total	$ 316	$ 293	$ 227	$ 57	$ 32	$ 925

Additional In-Licensed Programs

We may enter into additional license agreements relating to new product candidates.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

Not applicable because we are a smaller reporting company.

Item 8. ***Financial Statements and Supplemental Data***

See pages F-1 through F-25.

Item 9. ***Changes In and Discussions with Accountants on Accounting and Financial Disclosures***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Disclosure Controls and Procedures

Our management has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Principal Executive Officer and Principal Financial Officer has conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2016.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of our internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework* (2013). Based on the assessment, management concluded that, as of December 31, 2016, our internal controls over financial reporting were effective based on those criteria.

Our management, including our Principal Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and procedures and our internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the last quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Below is certain information regarding our directors and executive officers.

Name	Age	Position	Served as an Officer or Director Since
Jeffrey Wolf	53	Chairman, Chief Executive Officer and Director	2008
Jeff T. Hutchins, Ph. D.	58	Chief Scientific Officer /Senior Vice President Pre-Clinical Development	2017
Ann A. Rosar	64	Vice President of Finance	2016
John Monahan, Ph.D.	70	Director	2009
John K.A. Prendergast, Ph.D.	62	Director	2016
Edward B. Smith	41	Director	2009

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

Mr. Wolf founded Heat Biologics in August 2008. Mr. Wolf served from June 1997 to March 2011, as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several biomedical companies. Mr. Wolf's start-ups include Avigen, a gene therapy company where he was a co-founder and director; TyRx Pharma, a company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; EluSys Therapeutics, a 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 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 novel anti-infective biologic and drug candidates targeting specific pathogens that cause serious infections and other diseases.

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.

Jeff T. Hutchins, Ph.D., ***Chief Scientific Officer and Senior Vice President Pre-Clinical Development***

Dr. Hutchins joined our company on January 1, 2017 and oversees our research efforts, bringing over 24 years of research and clinical development experience from both large pharmaceutical and biotechnology companies. Most recently and since 2012, Dr. Hutchins served as Vice President of Preclinical Research for Peregrine Pharmaceuticals, Inc., a biopharmaceutical company developing therapeutics to fight cancer and infectious diseases. Dr. Hutchins was responsible for building out the research program for Peregrine's lead product candidate, bavituximab, a chimeric monoclonal antibody designed to target phosphatidylserine. Prior to joining Peregrine in 2012, from 2001 until 2012, Dr. Hutchins served as Vice President, Preclinical Development at Inhibitex Inc, which was acquired by Bristol-Myers Squibb. From 1991 to 2000, Dr. Hutchins held several senior scientist positions in Discovery Research at Burroughs Wellcome and Glaxo Wellcome, with a visiting professor appointment at Rush Medical College.

Dr. Hutchins earned a B.S. in Biology from Oral Roberts University, a Ph.D. in Biomedical Sciences from the University of Texas, Health Science Center at the M.D. Anderson Cancer Center and conducted postdoctoral training in the University of Southern California's Department of Microbiology at the Norris Cancer Center. Dr. Hutchins' publications and patents span the fields of oncology, infectious disease, osteoarthritis and immunology.

Ann A Rosar, M.B.A., ***Vice President of Finance, Controller and Secretary***

Ms. Rosar joined our company as Controller January 2015 and has over twenty years of experience in finance with publicly held companies and more than fifteen years of experience regarding regulatory reporting requirements. Prior to serving as Heat's Controller, Ms. Rosar served as Manager of Financial Reporting and Accounting for LipoScience, Inc. (acquired by LabCorp), a provider of specialized cardiovascular diagnostic tests, from 2013 to 2015. From 2007 until 2013 she served in various roles at DARA Biosciences, Inc. (now Midatech Pharma US), an oncology supportive care pharmaceutical company, including the Vice President of Finance, Chief Accounting Officer and Controller. Ms. Rosar was the Manager of Financial Reporting and Accounting with Cicero, Inc. (formerly Level 8 Systems), a provider of business integration software, from June 2000 until November 2007, where she was responsible for Securities and Exchange Commission reporting, audits and budget analysis. Prior to that position, she served as Senior Financial Analyst-Business Operations for Nextel Communications.

Ms. Rosar received a M.B.A. in Finance from the University of Houston and received her undergraduate degrees from North Carolina State University.

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

Dr. Monahan has served on our Board since November 2009 and is currently a consultant to Synthetic Biologics, Inc., a clinical stage company developing therapeutics to protect the gut microbiome while targeting pathogen-specific diseases focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses (NYSE MKT: SYN). 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 Scientific Advisory Board member of Agilis Biotherapeutics. He is also a board member of a number of Irish biotech companies including Genable, Cellix, Luxcel, and GK Technologies.

We selected Dr. Monahan to serve on our Board because he brings 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.

John K. A. Prendergast, Ph.D., ***Director***

Dr. Prendergast has served on our Board since April 2016. Dr. Prendergast is co-founder of Palatin Technologies, Inc. ("Palatin"), a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential (NYSE MKT: PTN). Dr. Prendergast has been Chairman of the Board of Palatin since June 14, 2000, and a director since August 1996. Dr. Prendergast has been president and sole stockholder of Summercloud Bay, Inc., an independent consulting firm providing services to the biotechnology industry, since 1993. Dr. Prendergast is a director and executive chairman of the board of directors of Antyra, Inc., a privately-held biopharmaceutical firm. He was previously a member of the board of the life science companies AVAX Technologies, Inc., Avigen, Inc. and MediciNova, Inc. From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr. Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

We selected Dr. Prendergast to serve on our Board because he brings extensive industry experience in corporate development and finance in the life sciences field. His prior service on other publicly traded company boards provides experience relevant to good corporate governance practices.

Edward B. Smith, III, *Director*

Mr. Smith has served on our Board since November 2010. Since January 1, 2015, Mr. Smith has also been Managing Member of Aristar Capital Management, LLC, a New York-based investment firm founded in 2015. From January 2015 until May 2016, Mr. Smith also served as the Chief Executive Officer of Agritech Worldwide, Inc. ("Agritech," formerly Z Trim Holdings Inc.) (OTCPink: FBER), a manufacturer of environmentally friendly agricultural functional ingredients, and has been a board member of Agritech since 2009. From April 2005 through December 2014, Mr. Smith served as the Managing Partner of Brightline Capital Management, LLC ("BCM"), a New York-based investment firm founded in 2005. 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.

We selected Mr. Smith to serve on our Board because he brings a strong business background to our 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 and Clinical Advisory Board

In addition to our Board, we also have a Scientific and Clinical Advisory board comprised of seven individuals. The Scientific and Clinical Advisory Board is responsible for providing advice and for assessing the scientific progress of our research and development efforts as well as to design and guide our clinical trials. We have entered into written agreements and confidentiality agreements with all of our members. The members of our Scientific and Clinical Advisory Board are compensated for their services.

Taylor Schreiber, M.D., Ph.D.

As Heat Biologics' former Chief Scientific Officer, Dr. Schreiber is co-inventor of significant elements of our*ImPACT* and *ComPACT* immunotherapy platforms. He most recently joined Shattuck Labs, Inc., a biotechnology company focused on developing technology exclusively licensed from Heat, as their Chief Scientific Officer. Taylor was also a scientific founder of Pelican Therapeutics, which developed a first-in-class agonist antibody to human TNFRSF25. As a cancer biologist and drug development scientist, Dr. Schreiber possesses over 15 years of laboratory experience in the discovery of novel therapeutic immuno-oncology compounds. Dr. Schreiber received his Ph.D. from the Sheila and David Fuente Program in cancer biology as well as his M.D. at the University of Miami Miller School of Medicine. In addition, he completed his post-doctoral fellowship with the original inventor of Heat's ImPACT technology platform, Eckhard R. Podack, M.D., Ph.D., studying the immunobiology of TNFRSF25. Dr. Schreiber has authored over 30 peer-reviewed tumor immunology and heat shock protein-based cancer immunotherapy publications.

Gary Acton, M.D.

Dr. Acton is a London-based clinician providing oncology drug development advice, predominantly to US and European biotechnology companies. Twenty years of pharmaceutical experience have left him with wide ranging clinical, commercial and corporate capabilities. He has expertise in all stages of drug development and through into the marketplace. This includes successful US NDA and European MAA approvals. Dr. Acton has been involved in drug development programs for most solid and hematological malignant indications. He has worked in North American, European, and Japanese pharmaceutical companies. Dr. Acton has served at Board level in both private and publicly traded entities. He originally studied medicine at Oxford and London Universities. Prior to moving into the pharmaceutical industry, Dr. Acton obtained a number of post-graduate qualifications while undergoing general medical and oncology training at a variety of London teaching hospitals.

Roger Cohen, M.D.

Dr. Cohen is Professor of Medicine at the University of Pennsylvania and Associate Director for Clinical Research for the Abramson Cancer Center. He is a graduate of Harvard Medical School and completed internal medicine and hematology training at Mount Sinai Hospital (NY) followed by research fellowships at the Memorial Sloan-Kettering Cancer Center and National Institutes of Health and a medical oncology fellowship at the National Cancer Institute. He was a medical officer at the FDA Center for Biologics from 1989-1994 where he was Deputy Director, Division of Monoclonal Antibodies. Prior to his arrival at Penn, Dr. Cohen was Director of the Clinical Trials Office at the University of Virginia Cancer Center in Charlottesville and then Director of the Phase 1 Program at the Fox Chase Cancer Center where he also served as interim Medical Oncology Department Chair for more than 2 years. He is an active investigator on a number of first-in-humans clinical trials with research interests that focus on evaluation of novel therapies, including monoclonal antibodies, immune therapies, and small molecule cell-signaling pathway inhibitors. He primarily sees patients with lung and head and neck cancer.

Llew Keltner, M.D., Ph.D.

Dr. Keltner has been the Chief Executive Officer of AgonOx, a biotech company developing OX40 agonists for use in cancer therapy. Dr. Keltner was the President of Novici Biotech, a privately-held gene and protein optimization firm. He is also Chief Executive Officer of EPISTAT, an international healthcare technology transfer, corporate risk management, and healthcare strategy company that he founded in 1972. Dr. Keltner was Chief Executive Officer and President of Light Sciences Oncology, a privately-held biotechnology company developing a late stage, light-activated therapy for hepatocellular cancer and other solid tumors from 2001 to 2010. From 1997 to 2004, Dr. Keltner was Chief Executive Officer of Metastat, a development-stage biotech company focused on cancer metastasis. He is currently a member of the American Society of Clinical Oncology, American Medical Association, International Association of Tumor Marker Oncology, American Association of Clinical Chemistry, and Drug Information Association. Dr. Keltner received an M.S. in Epidemiology and Biostatistics, a Ph.D. in Biomedical Informatics, and an M.D. from Case Western Reserve University in Cleveland, Ohio. Dr. Keltner has also authored several research publications.

Justin Stebbing, M.D., MA, FRCP, FRCPath, Ph.D.

Professor Stebbing is a member of the American Society for Clinical Investigation, a Fellow of the Royal College of Physicians and also of the Royal College of Pathologists. Originally, Dr. Stebbing 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 U.S., before returning to London to continue his training in oncology at The Royal Marsden. Dr. Stebbing then undertook a Ph.D., 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 600 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 and Editor-in-Chief of Oncogene.

Committees of the Board of Directors

The Board of Directors has a standing Audit Committee, Compensation Committee, Nominating and Governance Committee, Science and Technology Committee and Strategic Planning Committee. The following table shows the directors who are currently members or Chairman of each of these committees.

Board Members	Audit Committee	Compensation Committee	Nominating and Governance Committee	Science and Technology Committee	Strategic Planning Committee
Jeff Wolf	—	—	—	—	—
John Monahan, Ph.D.	Member	Chairman	Member	Member	Member
Edward Smith	Chairman	Member	Chairman	—	Member
John K.A. Prendergast, Ph.D.*	Member	Member	Member	Chairman	Chairman

* Dr. Prendergast serves as our independent Lead Director

Audit Committee

Our common stock is listed on the NASDAQ Capital Market. Under the rules of NASDAQ, independent directors must comprise a majority of a listed company's board of directors and all members our audit, compensation and nominating and corporate governance committees must 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. Monahan, Mr. Smith and Dr. Prendergast, representing three of our four 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.

Dr. Monahan, Mr. Smith, and Dr. Prendergast currently serve as members of the Audit Committee. The Board has determined that Dr. Monahan, Mr. Smith and Dr. Prendergast are each "independent" in accordance with the NASDAQ definition of independence and each is a "financial expert", as defined by the SEC regulations, and each has the related financial management expertise within the meaning of the NASDAQ rules. The primary purpose of the Audit Committee is to act on behalf of the Board of Directors in its oversight of all material aspects of our accounting and financial reporting processes, internal controls and audit functions, including our compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Pursuant to its charter, our Audit Committee reviews on an on-going basis for potential conflicts of interest, and approves if appropriate, all our "Related Party Transactions." For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404. In addition, the Audit Committee reviews, acts on and reports to the Board of Directors with respect to various auditing and accounting matters, including the selection of the Company's independent registered public accounting firm, the scope of the annual audits, fees to be paid to the independent registered public accounting firm, the performance of the Company's independent registered public accounting firm and the accounting practices of the Company and the Company's internal controls and legal compliance functions. The Committee also reviews, prior to publication, our quarterly earnings releases and our reports to the Securities and Exchange Commission on Forms 10-K and 10-Q. The Audit Committee operates pursuant to a written charter adopted by the Board of Directors, which is available on the Company's website at *www.heatbio.com*. The charter describes the nature and scope of responsibilities of the Audit Committee.

Compensation Committee

Our Compensation Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast, each of whom is deemed to be independent in accordance with the NASDAQ definition of independence. This Committee determines, approves, and reports to the Board of Directors on all elements of compensation of our executive officers. The Compensation Committee also has the power to prescribe, amend, and rescind rules relating to our stock incentive plans, to recommend the grant of options and other awards under the stock incentive plans, and to interpret the stock incentive plans.

The Compensation Committee operates under a formal charter that governs its duties and standards of performance. A copy of the charter is available on our website at *www.heatbio.com*.

Our Compensation Committee annually reviews the compensation program for our Chief Executive Officer and other members of senior management and then makes recommendations to the full board for determination. In each case, the Committee takes into account the results achieved by the executive, his or her future potential, and his or her scope of responsibilities and experience. During our fiscal year ended December 31, 2016, the committee evaluated the performance of our executives and considered the compensation levels and equity programs at comparable companies and related industries and the analysis of its outside consultant before it made its compensation recommendations to the full board, including recommendations regarding salary increases, awards of cash bonuses and awards of stock options.

The Committee administers our stock plan, including review and recommendation of long-term incentive compensation for each executive, director and employee, including grants of stock options. The Committee believes that this long-term incentive compensation aligns the interests of our executives with those of our stockholders and furthers executive retention.

The Committee also reviews and recommends to the Board of Directors appropriate director compensation programs for service as directors, committee chairs and committee members.

Nominating and Corporate Governance Committee

The Nominating and Governance Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast.

The functions performed by the Nominating and Governance Committee include:

- recommending to the Board of Directors, individuals for appointment or election as directors;
- recommending to the Board of Directors individuals for appointment to vacancies on any committee of the Board of Directors;
- recommending to the Board of Directors regarding any changes to the size of the Board of Directors or any committee;
- reporting to the Board of Directors on a regular basis; and
- performing any other duties or responsibilities expressly delegated to the committee by the Board of Directors relating to board or committee members.

Candidates for director should have certain minimum qualifications, including the ability to understand basic financial statements, being over 21 years of age, having relevant business experience (taking into account the business experience of the other directors), and having high moral character. The Committee retains the right to modify these minimum qualifications from time to time.

In evaluating an incumbent director whose term of office is set to expire, the Nominating and Governance Committee reviews such director's overall service to the Company during such director's term, including the number of meetings attended, level of participation, quality of performance, and any transactions with the Company engaged in by such director during his term.

When selecting a new director nominee, the Committee first determines whether the nominee must be independent for NASDAQ purposes or whether the candidate must qualify as an "Audit Committee financial expert." The Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm to assist in the identification of qualified director candidates. The Committee also will consider nominees recommended by our stockholders. The Nominating and Governance Committee does not distinguish between nominees recommended by our stockholders and those recommended by other parties. The Committee evaluates the suitability of potential nominees, taking into account the current board composition, including expertise, diversity and the balance of inside and independent directors. The Nominating and Governance Committee endeavors to establish a diversity of background and experience in a number of areas of core competency, including business judgment, management, accounting, finance, knowledge of our industry, strategic vision, research and development and other areas relevant to our business.

In considering any person recommended by one of our stockholders, the Committee will look for the same qualifications that it looks for in any other person that it is considering for a position on the Board of Directors. The Nominating and Governance Committee operates under a formal charter that governs its duties and standards of performance. A copy of the charter is available on our website at *www.heatbio.com*.

Science and Technology Committee

Our Science and Technology Committee is comprised of Dr. Monahan, and Dr. Prendergast, each of whom is deemed to be independent in accordance with the NASDAQ definition of independence. This Committee is responsible for examining our direction with respect to our research and development and our technology initiatives. The Science and Technology Committee operates pursuant to a written charter adopted by the Board of Directors, which is available on the Company's website at *www.heatbio.com*. The charter describes the nature and scope of responsibilities of the Science and Technology Committee.

Strategic Planning Committee

Our Strategic Planning Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast, each of whom is deemed to be independent in accordance with the NASDAQ definition of independence. This Committee oversees our strategic planning process, aids in identifying and evaluating corporate development opportunities and developing criteria to use in evaluating potential strategic opportunities. The Strategic Planning Committee operates pursuant to a written charter adopted by the Board of Directors, which is available on the Company's website at *www.heatbio.com*. The charter describes the nature and scope of responsibilities of the Strategic Planning Committee.

Board Leadership Structure

Mr. Wolf, the Company's Chief Executive Officer, also serves as Chairman of the Board. We have a separate, independent Lead Director. Although we do not have a formal policy addressing the topic, we believe that when the Chairman of the Board is an employee of the Company or otherwise not independent, it is important to have a separate Lead Director, who is an independent director.

Dr. Prendergast serves as the Lead Director. In that role, he presides over the Board's executive sessions, during which our independent directors meet without management, and he serves as the principle liaison between management and the independent directors of the Board. The Lead Director also:

- confers with the Chairman of the Board regarding Board meeting agenda;
- chairs meetings of the independent directors including, where appropriate, setting the agenda and briefing the Chairman of the Board on issues discussed during the meeting;
- oversees the annual performance evaluation of the CEO;
- consults with the Nominating and Governance Committee and the Chairman of the Board regarding assignment of Board members to various committees; and
- performs such other functions as the Board may require.

We believe the combination of Mr. Wolf as our Chairman of the Board and an independent director as our Lead Director is an effective structure for our company. The division of duties and the additional avenues of communication between the Board and our management associated with this structure provide the basis for the proper functioning of our Board and its oversight of management.

Risk Oversight

The Board has an active role, as a whole and also at the committee level, in overseeing management of our company's risks. The Board regularly reviews information regarding our company's strategy, finances and operations, as well as the risks associated with each. The Audit Committee is responsible for oversight of Company risks relating to accounting matters, financial reporting, internal controls and legal and regulatory compliance. The Audit Committee undertakes, at least annually, a review to evaluate these risks. The members then meet separately with management responsible for such area, including our Chief Financial Officer, and report to the Audit Committee on any matters identified during such discussions with management. In addition, the Compensation Committee considers risks related to the attraction and retention of talent as well as risks relating to the design of compensation programs and arrangements. In addition, the Nominating and Governance Committee manages risks associated with the independence of the Board. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board is regularly informed through committee reports about such risks. The full Board considers strategic risks and opportunities and regularly receives detailed reports from the committees regarding risk oversight in their respective areas of responsibility.

Code of Conduct

The Board of Directors has adopted a Code of Conduct that applies to our directors, executives (including its Chief Executive Officer and Vice President of Finance) and employees. The Code is posted on our website at *www.heatbio.com*.

2016 Director Compensation

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2016 regarding the compensation of our directors who at December 31, 2016 were not also named executive officers.

Name and Principal Position	Fees Earned or Paid in Cash	Option Awards	Other Compensation	Totals
John Monahan, PhD (1)	$ 60,583	$37,286	—	$ 97,869
John K. A. Prendergast, PhD (2)	$117,671	$17,072	—	$134,743
Edward Smith (1)	$ 66,375	$37,286	—	$103,661
Paul Belsky, MD (3)	$ 14,162	—	—	$ 14,162
Louis Bock (4)	$ 13,875	—	—	$ 13,875
Michael Kharitonov, PhD (4)	$ 13,000	—	—	$ 13,000

(1) The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to purchase 23,810 shares of common stock granted on January 17, 2016 to each individual board member with 100% vesting of the grant on the vesting commencement date of the following year, subject to remaining on the Board of Directors. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 9 to the Company's audited consolidated financial statements for the years ended December 31, 2016 and 2015.

(2) Dr. Prendergast joined the board on April 21, 2016. Dr. Prendergast was granted a ten year option exercisable for 40,000 shares of the Company's common stock at an exercise price of $0.65 per share. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 9 to the Company's audited consolidated financial statements for the years ended December 31, 2016 and 2015.

(3) Dr. Belsky resigned from the board April 21, 2016.

(4) Mr. Bock and Dr. Karitonov resigned from the board April 4, 2016.

As of December 31, 2016, the following table sets forth the number of aggregate outstanding option awards held by each of our directors who were not also named executive officers:

Name	Aggregate Number of Option Awards
John Monahan, Ph.D.	64,860
John K. A. Prendergast, PhD.	40,000
Edward Smith	57,251

Our Compensation Committee conducted an evaluation of the compensation of the members of our board of directors. In order to aid its decision-making, the Compensation Committee considered the compensation practices and the competitive market for directors at companies with which we compete for personnel and an independent compensation advisor was retained to conduct a study of our peer group compensation. Based substantially upon the results of the study, on January 2, 2017, each director who is not an employee received an option grant to purchase 90,000 shares of our common stock (having a value of $43,200) vesting on the one year anniversary of the grant date and for his services as lead independent director Dr. Prendergast received an additional option grant to purchase 90,000 shares of common stock. During the year ended January 2016, and anticipated to remain the same for the current year, directors who are not employees receive an annual cash fee of $35,000 as well as a cash fee of $8,000 for service on the Audit Committee and $5,000 for service on each of the Compensation and Nominating Committees. In addition, the Chairman of each of the Audit, Compensation and Nominating Committees will each receive an additional $12,500, $8,500 and $7,000, respectively. The Chairman of the Strategic Planning Committee receives a monthly fee of $7,500 and each member of the Strategic Planning Committee receives a fee of $1,000 per committee meeting attended. The Chairman of the Science and Technology Committee receives an annual fee of $10,000 and the other member of the Science and Technology committee receive an annual fee of $1,000 for services on that committee. The lead independent director receives a monthly fee of $6,250 for his services as lead independent director. In addition, on January 11, 2016, each director who is not an employee was granted an option exercisable for shares of common stock (having a value of $45,000) vesting on the one-year anniversary of the date of grant.

Item 11. ***Executive Compensation***

Set forth below is the compensation paid or accrued to our executive officers during the years ended December 31, 2016 and December 31, 2015 that exceeded $100,000.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (9)	Options (9)	Other (1)	Total
Jeffrey Wolf	2016	$ 404,583	$ 202,500(2)	$ 64,500	$ 198,396	$ —	$ 869,979
Chairman and CEO	2015	$ 395,000	$ 177,750(3)	$ —	$ 47,513	$ —	$ 620,263
Taylor Schreiber	2016	$ 300,000	$ —	$ —	$ 94,583	$ 75,000	$ 469,583
*Former Chief Scientific Officer (4)**	2015	$ 272,005	$ 95,202(3)	$ —	$ 187,390	$ —	$ 554,597
Ann A. Rosar	2016	$ 152,386	$ 40,000(2)	$ —	$ 18,834	$ 40,000	$ 251,220
Vice President of Finance (5)							
Timothy Creech	2016	$ 55,548	$ —	$ —	$ —	$ 142,500	$ 198,048
Former Chief Financial Officer (6)	2015	$ 24,542	$ —	$ —	$ 144,627	$ —	$ 169,169
Anil Goyal	2016	$ 65,899	$ —	$ —	$ —	$ 88,000	$ 153,899
Former Vice President of Business Development (7)	2015	$ 255,000	$ 51,000(3)	$ —	$ 47,513	$ —	$ 353,513
Melissa Price	2016	$ 145,125	$ —	$ —	$ —	$ —	$ 145,125
Former Vice President of Product Development (8)	2015	$ 250,000	$ 75,000(3)	$ —	$ —	$ —	$ 325,000

(1) Represents payment for 2016 Retention bonus accrued in 2016 and paid in 2017 and severance payments paid in 2016.
(2) This bonus was accrued in 2016 and paid in 2017.
(3) This bonus was accrued in 2015 and paid in 2016.
(4) Dr. Schreiber resigned as Chief Scientific Officer effective January 1, 2017, and now serves as Chairman of our Scientific and Advisory Board.
(5) Mrs. Rosar served as our Controller from January 2015 until her appointment on April 5, 2016 as our Vice President of Finance, Controller and Secretary.
(6) Mr. Creech resigned as our Chief Financial Officer effective April 5, 2016.
(7) Dr. Goyal resigned as our Vice President of Business Development effective April 5, 2016.
(8) Dr. Price resigned as our Vice President of Product Development effective July 29, 2016.
(9) For all stock options and stock awards, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC 718. Assumptions made in the calculation of these amounts are described in Note 9 to the Company's audited consolidated financial statements for the years ended December 31, 2016 and 2015.

* On January 1, 2017, Jeff T. Hutchins, Ph.D. was appointed Chief Scientific Officer and Senior Vice President of Pre-Clinical Development. Dr. Hutchins annual salary is $305,000 and he will be eligible for discretionary performance bonus payments of twenty-five percent (25%) of his base salary.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2016)

	Option Awards				Stock Awards	
Name and Principal Position	**Number of securities underlying unexercised options/ exercisable**	**Number of securities underlying unexercised options/ unexercisable**	**Option exercise price**	**Option expiration date**	**Number of shares or units of stock that have not vested**	**Market value of shares or units of stock that have not vested**
Jeffrey Wolf	10,965 (1)	—	$ 2.30	12/18/2019	—	—
Chairman and CEO	100,000 (2)	—	$ 8.62	6/11/2024	—	—
	6,250 (3)	6,250	$ 4.53	1/12/2025	—	—
	23,512 (4)	70,536	$ 2.47	1/11/2026	—	—
	75,000 (5)	—	$ 0.86	12/30/2026	56,250(6)	$ 48,375
Taylor Schreiber	35,412 (7)	14,588	$ 4.57	6/11/2024	—	—
Chief Scientific Officer	5,000 (8)	5,000	$ 4.53	1/12/2025	—	—
	12,395 (9)	22,605	$ 6.03	7/22/2025	—	—
	14,394(10)	43,173	$ 2.47	1/11/2026	—	—
Ann A. Rosar	4,791(11)	5,209	$ 4.53	1/12/2025	—	—
Vice President of	1,545(12)	4,635	$ 2.47	1/11/2026	—	—
Finance, Controller	3,750(13)	16,250	$ 0.66	4/5/2026	—	—
Tim Creech	—	—	—	—	—	—
Former Chief Financial Officer						
Anil Goyal	—	—	—	—	—	—
Vice President of Business Development						
Melissa Price	—	—	—	—	—	—
Vice President of Product Development						

(1) All shares are fully vested as of December 31, 2013.
(2) Issued on June 11, 2014, these options vest over a two year period and will be fully vested in January 2016.
(3) Issued on January 12, 2015, these options vest over a four year period and will be fully vested in December 2018.
(4) Issued on January 11, 2016, these options vest over a four year period and will be fully vested in December 2019.
(5) Issued on December 30, 2016, these options vest over a four year period and will be fully vested in January 2020.
(6) Issued on December 30, 2016, 18,750 restricted stock units vested December 30, 2016; 18,750 will vest December 30, 2017; 18,750 will vest December 30, 2018; and 18,750 will vest December 30, 2019. Amount represents the value of shares at December 30, 2016.
(7) Issued on June 11, 2014, these shares vest over a 46 month period and will be fully vested in February 2018.
(8) Issued on January 12, 2015, these options vest over a four year period and will be fully vested in December 2018.
(9) Issued on July 23, 2015, these options vest over a four year period and will be fully vested in July 2019.
(10) Issued on January 11, 2016, these options vest over a four year period and will be fully vested in December 2019.
(11) Issued January 12, 2015, these shares vest over a four year period and will be fully vested in January 2019.
(12) Issued on January 11, 2016, these options vest over a four year period and will be fully vested in January 2019.
(13) Issued on April 5, 2016, these options vest over a four year period and will be fully vested in March 2020.

The chart above does not include the grant of options exercisable for 125,000, 70,000, and 200,000 shares of common stock issued to each of Mr. Wolf, Mrs. Rosar, and Dr. Hutchins, respectively, in January 2017. Also, on January 3, 2017, Mr. Wolf and Mrs. Rosar were granted 125,000 and 70,000 Restricted Stock Units which vest 25% on grant date, and 25% on each anniversary of grant date thereafter.

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, and further amended on each of January 20, 2014 and January 11, 2016 and January 1, 2017. Mr. Wolf receives an annual base salary of $417,150 per year. He also may receive, at the sole discretion of the board, an additional cash performance-based bonuses equal to up to 50% of his then outstanding base salary at the end of each year and a discretionary equity award, with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. 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 12 month's 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 January 2, 2017, we approved the entry into a four-year employment agreement, effective as of January 1, 2017, with Jeff T. Hutchins, Ph.D. (the "Hutchins Employment Agreement"), who was appointed to serve as the Chief Scientific Officer and Senior Vice President of Pre-Clinical Development of the Company. Pursuant to the Hutchins Employment Agreement, Dr. Hutchins will be entitled to an annual base salary of $305,000 and will be eligible for discretionary performance bonus payments of twenty-five percent (25%) of his base salary. Additionally, we granted Dr. Hutchins an option to purchase 200,000 shares of our common stock, with an exercise price equal to $0.88 per share. These options will vest pro rata, on a monthly basis, over forty-eight months.

If Dr. Hutchins' employment is terminated for any reason, he or his estate as the case may be, is entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Hutchins Accrued Obligations"); provided, however, that if his employment is terminated by us without Just Cause (as defined in the Hutchins Employment Agreement) then in addition to paying the Hutchins Accrued Obligations, (i) we will shall continue to pay his then current base salary for a period of six (6) months; and (ii) the vesting on all unvested options shall be accelerated so that all options shall become fully vested. If his employment is terminated within one year of a Change of Control (as defined in our Amended and Restated 2014 Stock Incentive Plan), he will be paid his then current base salary for a period of nine (9) months.

On April 5, 2016, we entered into a four-year employment agreement with Ann Rosar to serve as our Vice President of Finance, Controller and Corporate Secretary, which was amended on January 1, 2017 (the "Rosar Employment Agreement"). Pursuant to the Rosar Employment Agreement, Ms. Rosar receives an annual base salary of $200,000 and is eligible for a discretionary performance bonus. Ms. Rosar was also granted a ten year option exercisable for 20,000 shares of our Common Stock, vesting pro rata on a monthly basis over a four year period. In addition, if Ms. Rosar's employment is terminated for any reason, she or her estate as the case may be, are entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by her to the extent not previously paid ("Rosar Accrued Obligations"); provided, however, that if her employment is terminated by the Company without Just Cause (as defined in the employment agreement) or by Ms. Rosar for Good Reason (defined as a material breach of the terms of the employment agreement by us, which breach is not cured within thirty (30) days) then in addition to paying the Accrued Obligations, we will continue to pay her then current base salary for a period of four (4) months.

Dr. Schreiber currently serves as the Chairman of our Scientific Advisory Board. Effective July 23, 2015, Taylor Schreiber, M.D., Ph.D., was appointed to serve as our Chief Scientific Officer and from March 3, 2014 until July 23, 2015, Dr. Schreiber served as our Vice President of Research and Development. In connection with his appointment, Dr. Schreiber entered into a four-year employment agreement with us, which was amended January 12, 2015 and further amended on July 23, 2015 and January 11, 2016. Pursuant to the employment agreement, Dr. Schreiber receives an annual base salary of $300,000 and will be eligible for discretionary cash performance bonus payment of thirty-five percent (35%) of his base salary and a discretionary equity award with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. Dr. Schreiber resigned his position as Chief Scientific Officer effective January 1, 2017.

Effective November 30, 2015, we appointed Timothy Creech as our Chief Financial Officer. In connection with his appointment, Mr. Creech entered into a four-year employment agreement with us, which was amended on January 11, 2016. Pursuant to his agreement, Mr. Creech received an annual base salary of $285,000 and was eligible for a discretionary cash performance bonus payment of thirty five percent (35%) of his base salary and a discretionary equity award with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. Effective April 5, 2016, we entered into a severance agreement with Mr. Creech in accordance with the terms of his employment agreement. Pursuant to the agreement, Mr. Creech's received $142,500, which equaled six month's severance pay upon termination not for cause (as defined in the agreement). The severance agreement also contained additional provisions that are customary for agreements of this type, including confidentiality, non-competition and non-solicitation provisions

Effective December 16, 2013, we appointed Anil K. Goyal, Ph.D. as our Vice President of Business Development. In connection with his appointment, Dr. Goyal entered into a four-year employment agreement with us (the "Goyal Employment Agreement"), which was amended January 12, 2015 and further amended on January 11, 2016. Pursuant to the Goyal Employment Agreement, Dr. Goyal received an annual base salary of $255,000 and was eligible for a discretionary cash performance bonus payment of thirty percent (30%) of his base salary and a discretionary equity award with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. Effective April 5, 2016, we entered into a severance agreement with Dr. Goyal in accordance with the terms of his employment agreement. Pursuant to the agreement, Dr. Goyal received $85,000, which equaled four month's severance.

Effective October 1, 2013, we appointed Melissa Price, Ph.D. as our Vice President of Clinical and Regulatory Affairs. In connection with her appointment, Dr. Price entered into a four-year employment agreement with us (the "Price Employment Agreement"), which was amended on January 20, 2014 and further amended on January 12, 2015, July 23, 2015 and January 11, 2016. On July 23, 2015, Dr. Price was appointed our Vice President of Product Development. Pursuant to the Price Employment Agreement, Dr. Price receives an annual base salary of $250,000 and will be eligible for a discretionary cash performance bonus payment of thirty percent (30%) of her base salary and a discretionary equity award with the actual amount of her bonus to be increased or decreased in the sole discretion of the Board of Directors. Dr. Price resigned as our Vice President of Clinical and Regulatory Affairs effective July 29, 2016.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers, directors and persons who beneficially own more than 10 percent of a registered class of the Heat Biologics' equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. Such officers, directors and persons are required by SEC regulation to furnish us with copies of all Section 16(a) forms that they file with the SEC.

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no Form 5s were required for those persons, we are not aware of any failures to file reports or report transactions in a timely manner during the year ended December 31, 2016.

Code of Ethics

We have long maintained a Code of Conduct that is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management that applies to our Chief Executive Officer, Vice President of Finance/Controller. We undertake to provide a printed copy of these codes free of charge to any person who requests. Any such request should be sent to our principal executive offices attention: Corporate Secretary.

Item 12. ***Security Ownership of Certain Beneficial Owners***

The following table sets forth information, as of March 28, 2017, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons know to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group. As of March 28, 2017, we had 33,526,992 shares of common stock outstanding.

Principal Stockholders Table

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. 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	Common Stock	Shares subject to Options (1)	Total Number of Shares Beneficially Owned	Percentage Ownership
Executive Officers & Directors				
Timothy Creech, Former Chief Financial Officer	—	—	—	*
Anil Goyal, Former Vice President of Business Development	—	—	—	*
Jeff T. Hutchins, Chief Scientific Officer and Senior Vice President of Pre-Clinical Development (2)	—	16,666	16,666	*
John Monahan, Ph.D. (Director)	1,211	64,860	66,071	*
John K. A. Prendergast, Ph.D. (Director)	—	11,666	11,666	*
Melissa Price, Former Vice President of Product Development	692	—	692	*
Ann A. Rosar Vice President Finance	10,736	19,479	30,215	*
Taylor Schreiber, M.D., PhD Chairman of Scientific Advisory Board (3)	39,132	77,724	116,856	*
Edward Smith (Director) (4)	697,303	57,251	754,554	*
Jeffrey Wolf (Director, CEO, Treasurer & Secretary) (5)	1,287,396	165,887	1,453,283	4.3%
All Executive Officers & Directors, as a group (10 persons)	2,036,470	413,533	2,450,003	7.2%
5% Stockholders				
None				

* less than 1%

(1) Represents shares subject to options that are vested and exercisable within 60 days of March 28, 2017.

(2) Dr. Hutchins was appointed Chief Scientific Officer and Senior Vice President of Pre-Clinical Development on January 1, 2017.

(3) Dr. Schreiber resigned as the company's Chief Scientific Officer on December 31, 2016 and now serves as the Chairman of the company's Scientific and Clinical Advisory Board. Dr. Schreiber and an entity controlled by Dr. Schreiber have been issued an aggregate of 39,132 shares of common stock that are included in the number of shares beneficially owned by Dr. Schreiber.

(4) Information obtained from a Schedule 13D/A filed on February 14, 2017 with the Securities and Exchange Commission filed on behalf of Aristar Capital Management, LLC of which Mr. Smith disclaims beneficial ownership of 697,303 shares of common stock, 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.

(5) 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. Includes 3,660 shares purchased May 2014 and 1,221 shares converted from Series B, does not include 86,957 shares of common stock beneficially owned by Mr. Wolf's children's trust of which Mr. Wolf is not the trustee. 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.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

Pursuant to our charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our "Related Party Transactions" as required by of NASDAQ Rule 4350(h). For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404. The Company had a related party receivable balance of $103,017 and $58,017 as of December 31, 2016 and 2015, respectively. This related party receivable reflects a percent of labor that our former Chief Scientific Officer, Dr. Schreiber performed on the behalf of our former subsidiary Pelican.

The following is a summary of transactions since January 1, 2015 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 most recent completed fiscal year ($80,000) 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 Annual Report on Form 10-K entitled "Management—Non-Employee Director Compensation" and "Management — Executive Compensation."

Subsequent to year end, we entered into the Purchase Agreement with Pelican, and the Majority Pelican Stockholders to purchase outstanding capital stock of Pelican. Jeff Wolf, through one or more of his affiliated entities, and Edward Smith and entities controlled by Mr. Smith are Participating Pelican Stockholders and have agreed to sell a minimum of 80% and a maximum of 100% of their shares of the capital stock of Pelican in order to meet the 80% closing condition, on the same terms as the other Participating Pelican Stockholders. Mr. Wolf is the managing member of a limited liability company that owns 60.1% of the outstanding capital stock of Pelican and Mr. Wolf directly and through entities owned by him owns 31.6% of the membership interests of the limited liability company. Mr. Smith directly and through entities that he controls holds approximately 10.2% of Pelican's outstanding capital stock and Mr. Smith directly and indirectly through an entity he controls owns an aggregate of 23.1% of the membership interests of the limited liability company. Taylor Schreiber, M.D., Ph.D holds less than 1% of Pelican's total outstanding capital stock and indirectly through an entity he controls, owns 5% of the limited liability company. Dr. Schreiber has agreed to sell a minimum of 80% and a maximum of 100% of his shares of the capital stock of Pelican in order to meet the 80% closing condition, on the same terms as the other Participating Pelican Stockholders. John Monahan, Ph.D owns 0.46% of the limited liability company. In addition, a trust for which Mr. Wolf does not serve as the trustee for the benefit of Mr. Wolf's children directly owns 2.2% of Pelican's total outstanding capital stock and owns 10% of the membership interests of the limited liability company. Mr. Wolf disclaims beneficial ownership of all shares held by the trust.

On January 2, 2017, our named executive officers were awarded the following 2016 year-end bonus compensation: Jeffrey A. Wolf, our Chief Executive Officer, was granted options to purchase 200,000 shares of our common stock of which 75,000 were granted December 30, 2016, 200,000 restricted stock units of which 75,000 were granted December 30, 2016 and received a cash bonus in the amount of $202,500; Mrs. Rosar was granted options to purchase 75,000 shares of our common stock, 75,000 restricted stock units, and received a cash bonus in the amount of $40,000. The December 2016 stock options have an exercise price of $0.86 per share, which is the closing price of our common stock on the grant date (December 30, 2016). The stock options granted January 2, 2017 have an exercise price of $0.87 per share, which is the closing price of our common stock on the grant date (January 3, 2017), vest pro rata, on a monthly basis, over a four (4) year period and expire ten (10) years from the date of the grant, unless terminated earlier. The restricted stock units immediately vest 25% on the date of grant and then 25% on the anniversary date of grant each year thereafter.

On January 2, 2017, our non-executive directors, John Monahan and Ed Smith were granted options to purchase 90,000 shares of our common stock, and John Prendergast was granted options to purchase 180,000 shares of our common stock. The stock options granted have an exercise price of $0.87, which is the closing price of our common stock on the grant date (January 3, 2017), vest on January 2, 2018 and expire ten (10) years from the date of the grant, unless terminated earlier.

On January 1, 2017, Dr. Jeff Hutchins as part of his employment agreement was granted 200,000 options and $66,000 sign-on bonus. The stock options granted have an exercise price of $0.87 per share, which is the closing price of our common stock on the grant date (January 3, 2017), vest pro rata, on a monthly basis, over a four (4) year period and expire ten (10) years from the date of the grant, unless terminated earlier.

In addition, on January 12, 2015, our named executive officers were awarded the following 2014 year-end bonus compensation: Jeffrey A. Wolf, our Chief Executive Officer, was granted options to purchase 12,500 shares of the Company's common stock and received a cash bonus in the amount of $127,500; Dr. Goyal was granted options to purchase 12,500 shares of the Company's Common Stock and received a cash bonus in the amount of $49,500; Dr. Price received a cash bonus in the amount of $47,250; and Dr. Schreiber was granted options to purchase 10,000 shares of Common Stock and received a cash bonus in the amount of $39,483. The stock options granted have an exercise price of $4.53, which is the closing price of the Common Stock on the grant date (January 12, 2015), vest immediately, pro rata, on a monthly basis, over a four (4) year period and expire ten (10) years from the date of the grant, unless terminated earlier.

Item 14.
Principal Accountant Fees and Services

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2016 and 2015 by BDO USA, LLP.

	December 31, 2016	December 31, 2015
Audit Fees and Expenses (1)	$ 169,500	$ 128,100

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a)(1) The following financial statements are included in this Annual Report on Form 10-K for the fiscal years ended December 31, 2016 and 2015.

1. Report of Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2016 and 2015
3. Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2016 and 2015
4. Consolidated Statements of Stockholders' Equity for the years ended December 31, 2016 and 2015
5. Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015
6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) The following exhibits are either filed as part of this report or are incorporated herein by reference:

Exhibit No.	Description
1.1	Form of Underwriting Agreement between Heat Biologics, Inc. and Aegis Capital Corp., as representative of the several underwriters Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)
1.2	Underwriting Agreement, dated March 10, 2015, between Heat Biologics, Inc. and Aegis Capital Corp. Previously filed as an exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2015 (File No. 001-35994).
1.3	Form of Underwriting Agreement, dated Roth Capital Partners, LLC and Aegis Capital Corp., as representatives of several underwriters Previously filed as an exhibit to the Company's registration statement on Form S-1 filed on March 15, 2016 (File No. 333-2209079)
1.4	At Market Issuance Sales Agreement, by and between Heat Biologics, Inc. and FBR Capital Markets & Co. dated August 15, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994)
1.5	Underwriting Agreement, dated March 23, 2017, between Heat Biologics, Inc. and Aegis Capital Corp. Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 24, 2017 (File No. 001-35994)
3.1	Certificate of Incorporation filed on June 10, 2008 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
3.2	Amended and Restated Bylaws, as currently in effect Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
3.3	Amended and Restated Certificate of Incorporation filed on October 16, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
3.4	Second Amended and Restated Certificate of Incorporation filed on December 16, 2011 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
3.5	Third Amended and Restated Certificate of Incorporation, as currently in effect Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
3.6	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on May 29, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365).
3.7	Amended and Restated Bylaws dated January 11, 2016Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)

4.1	2009 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.2	First Amendment of the 2009 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.3	Second Amendment of the 2009 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.4	Third Amendment of the 2009 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.5	Fourth Amendment of the 2009 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.6	Warrant issued to Square 1 Bank Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.7	Warrant issued to North Carolina Biotechnology Center Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)
4.8	Specimen Common Stock Certificate of Heat Biologics, Inc. Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
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)## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
4.10	Form of Representative's Warrant Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365).
4.11	Amendment to Stock Warrant with North Carolina Biotechnology Center Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)
4.12	2014 Stock Incentive Plan## Previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on June 13, 2014 (File No. 333-196763)
4.13	Warrant issued to Square 1 Bank Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 25, 2014 (File No. 001-35994)
4.14	First Amendment to Loan and Security Agreement Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on June 24, 2015 (File No. 001-35994).
4.15	Form of Warrant Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 3, 2016 (File No. 001-35994)
10.1	License Agreement (UMJ110) between the University of Miami and Heat Biologics, Inc. effective February 18, 2011** Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.2	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008**Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.3	License Agreement (143) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 11, 2011** Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
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**Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.5	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011**Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.6	Promissory Note with North Carolina Biotechnology Center dated December 14, 2011 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.7	Loan Agreement with North Carolina Biotechnology Center dated December 14, 2011 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.8	Common Stock Subscription Agreement between the University of Miami and Heat Biologics I, Inc. dated July 7, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.9	Employment Agreement with Jeffrey Wolf dated December 18, 2009## ## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)

10.10	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011## Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.11	Non-Exclusive Evaluation and Biological Material License Agreement with American Type Culture Collection effective April 12, 2011** Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.12	Manufacturing Services Agreement with Lonza Walkersville, Inc. dated as of October 20, 2011 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.13	Assignment and Assumption Agreement dated June 26, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.14	Termination Agreement UM97-114 dated June 26, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.15	Loan and Security Agreement with Square 1 Bank dated August 7, 2012 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.16	Amendment to License Agreement (UM97-14) dated April 29, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.17	First Amendment to Loan and Security Agreement with Square 1 Bank dated November 30, 2012 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.18	Second Amendment to License Agreement (UMSS-114) dated August 11, 2009 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.19	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.20	Second Amendment to Loan and Security Agreement with Square 1 Bank dated January 14, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.21	Third Amendment to Loan and Security Agreement with Square 1 Bank dated February 28, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.22	Fourth Amendment to Loan and Security Agreement with Square 1 Bank dated March 19, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.23	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.24	Fifth Amendment to the Loan and Security Agreement with Square 1 Bank dated April 18, 2013 Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365)
10.25	Form of Lock-up Agreement Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)
10.26	Form of Agreement with Series B Preferred Stockholders to amend Stock Purchase Agreement Previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365)
10.27	Employment Agreement, dated as of October 1, 2013, by and between Melissa Price and the Company## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on October 1, 2013
10.28	Employment Agreement, dated as of December 16, 2013, by and between Anil K. Goyal and the Company## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on December 19, 2013 (File No. 001-35994)
10.29	Amendment to Employment Agreement, dated as of January 20, 2014 between the Company and Jeffrey Wolf## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994)
10.30	Amendment to Employment Agreement, dated as of January 20, 2014 between the Company and Melissa Price## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994)

10.31	Employment Agreement, dated as of March 3, 2014 between the Company and Taylor Schreiber ## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 5, 2014 (File No. 001-35994)
10.32	Lease Agreement dated January 24, 2014 Previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2014 (File No. 001-35994)
10.33	License Agreement (UMK-161) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective March 4, 2014** Previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2014 (File No. 001-35994)
10.34	Loan and Security Agreement dated August 22, 2014 by and between Square 1 Bank, the Company and Heat Biologics I, Inc., Heat Biologics III, Inc. and Heat Biologics IV, Inc. Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 25, 2014 (File No. 001-35994)
10.35	Amendment to Employment Agreement dated January 12, 2015 between the Company and Melissa Price## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994)
10.36	Amendment to Employment Agreement dated January 12, 2015 between the Company and Anil Goyal## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994).
10.37	Amendment to Employment Agreement dated January 12, 2015 between the Company and Taylor Schreiber## Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994)
10.38	Severance Agreement, dated as of March 9, 2015 with Matthew Czajkowski Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 10, 2015 (File No. 001-35994)
10.39	First Amendment to Lease Previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 27, 2015 (File No. 001-35994)
10.40	Second Amendment to Lease Previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 27, 2015 (File No. 001-35994)
10.41	Amendment to Employment Agreement between the Company and Taylor Schreiber, M.D., Ph.D., dated July 23, 2015 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994)
10.42	Amendment to Employment Agreement between the Company and Melissa Price, Ph.D., dated July 23, 2015 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994)
10.43	Amended and Restated Heat Biologics, Inc. 2014 Stock Incentive Plan Previously filed as Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 22, 2015)
10.44	Form of Incentive Stock Option Agreement under the 2014 Stock Incentive Plan, as amended Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994)
10.45	Form of Non-Statutory Stock Option Agreement under the 2014 Stock Incentive Plan, as amended Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994)
10.46	Employment Agreement, dated as of November 30, 2015 between the Company and Timothy Creech Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on December 1, 2015 (File No. 001-35994)
10.47	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 11, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)
10.48	Amendment to Employment Agreement between the Company and Melissa Price, dated January 11, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)
10.49	Amendment to Employment Agreement between the Company and Taylor Schreiber, dated January 11, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)
10.50	Amendment to Employment Agreement between the Company and Anil Goyal dated January 11, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)

10.51	Amendment to Employment Agreement between the Company and Timothy Creech dated January 11, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994)
10.52	Second Amendment to Loan And Security Agreement between the Company and Pacific Western Bank and Heat Biologics, Inc., Heat Biologics I, Inc., Heat Biologics III, Inc., and Heat Biologics IV, Inc. dated February 29, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 3, 2016 (File No. 001-35994)
10.53	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated April 1, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.54	Amendment to Employment Agreement between the Company and Melissa Price, dated April 1, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.55	Amendment to Employment Agreement between the Company and Taylor Schreiber, dated April 1, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.56	Employment Agreement between the Company and Ann Rosar, dated April 1, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.57	Severance Agreement between the Company and Timothy Creech, dated April 5, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.58	Severance Agreement between the Company and Anil Goyal, dated April 5, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
10.59	Amendment to License Agreement (UM97-14) between the University of Miami and Heat Biologics, Inc. effective July 26, 2016 Previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994)
10.60	Form of Indemnification Agreement by and between Heat Biologics, Inc. and its directors and officers Previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994)
10.61	Exclusive License Agreement (UMIP-114/Strbo) between the University of Miami and Zolovax, Inc., a wholly-owned subsidiary of Heat Biologics effective October 24, 2016 Previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on November 10, 2016 (File No. 001-35994)
10.62	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 1, 2017 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994)
10.63	Amendment to Employment Agreement between the Company and Ann Rosar, dated January 1, 2017 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994)
10.64	Employment Agreement between the Company and Jeff T. Hutchins, dated January 1, 2017 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994)
10.65	Form of Restricted Stock Unit Award Agreement Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994)
10.66	Stock Purchase Agreement by and among Heat Biologics, Inc., with Pelican Therapeutics, Inc. (“Pelican”), and certain stockholders in Pelican Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 8, 2017 (File No. 001-35994)
10.67	First Amendment to Exclusive License Agreement between The Regents of The University of Michigan and Heat Biologics, Inc. (UM File Number 3680) dated December 1, 2016*
10.68	First Amendment to Stock Purchase Agreement to Stock Purchase Agreement dated March 29, 2017 by and among Heat Biologics, Inc., Pelican Therapeutics, Inc. and Josiah Hornblower as representative of the Stockholders*
21.1	List of Subsidiaries *
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP) *
31.1	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) *
31.2	Certification of Ann Rosar, Principal Financial and Principal Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a) *
32.1	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *

32.2	Certification Ann Rosar, Principal Financial and Principal Accounting Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *

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* Filed herewith.
Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.
** Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Item 16. ***Form 10-K Summary***

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned.

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Jeffrey Wolf
Chief Executive Officer and Director
(Principal Executive Officer)
Date: March 31, 2017

By: /s/ Ann A. Rosar
Ann A. Rosar
Vice President of Finance
(Principal Financial and Principal Accounting Officer)
Date: March 31, 2017

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey Wolf Jeffrey Wolf	Chief Executive Officer, President and Chairman (Principal Executive Officer)	March 31, 2017
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 31, 2017
/s/ John K.A. Prendergast, Ph.D. John K.A. Prendergast, Ph.D.	Director	March 31, 2017
/s/ Edward B. Smith Edward B. Smith	Director	March 31, 2017

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Heat Biologics, Inc.
Durham, North Carolina

We have audited the accompanying consolidated balance sheets of Heat Biologics, Inc. ("the Company") as of December 31, 2016 and 2015 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2016**,** in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 31, 2017

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	December 31, 2016	December 31, 2015
Current Assets		
Cash and cash equivalents	$ 7,842,667	$ 4,939,955
Investments, held to maturity (net)	—	6,689,643
Accounts receivable	82,305	—
Prepaid expenses and other current assets	338,049	869,158
Total Current Assets	8,263,021	12,498,756
Property and Equipment, net	359,592	445,733
Other Assets		
Restricted cash	101,171	101,151
Deposits	69,798	69,798
Related party receivable	103,017	58,017
Deferred financing costs	—	44,307
Total Other Assets	273,986	273,273
Total Assets	$ 8,896,599	$ 13,217,762
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 290,058	$ 1,980,676
Accrued expenses and other liabilities	1,305,173	1,846,907
Current portion of long term debt	—	3,133,958
Total Current Liabilities	1,595,231	6,961,541
Long Term Liabilities		
Long term debt, net of discount and current portion	—	3,611,743
Other long term liabilities	461,434	149,748
Total Liabilities	2,056,665	10,723,032
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $.0002 par value; 50,000,000 shares authorized, 26,204,390 and 8,424,641 issued and outstanding at December 31, 2016 and 2015, respectively	4,926	1,366
Additional paid-in capital	65,868,541	48,566,451
Accumulated deficit	(57,004,655)	(44,430,703)
Accumulated other comprehensive loss	(72,231)	(86,584)
Total Stockholders' Equity - Heat Biologics, Inc	8,796,581	4,050,530
	(1,956,647)	(1,555,800)
Non-Controlling Interest		
Total Stockholders' Equity	6,839,934	2,494,730
Total Liabilities and Stockholders' Equity	$ 8,896,599	$ 13,217,762

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Operations and Comprehensive Loss

	Year ended, December 31,	
	2016	2015
Revenue:		
Licensing revenue	$ 341,643	$ —
Operating expenses:		
Research and development	9,330,677	16,666,335
General and administrative	4,138,285	4,356,381
Total operating expenses	13,468,962	21,022,716
Loss from operations	(13,127,319)	(21,022,716)
Interest income	31,142	66,091
Other income, net	670,781	198,369
Interest expense	(549,403)	(363,629)
Total non-operating income (expenses), net	152,520	(99,169)
Net loss	(12,974,799)	(21,121,885)
Net loss - non-controlling interest	(400,847)	(826,629)
Net loss attributable to Heat Biologics, Inc.	$ (12,573,952)	$ (20,295,256)
Net loss per share attributable to Heat Biologics, Inc.-		
basic and diluted	$ (0.71)	$ (2.53)
Weighted-average number of common shares used in net loss per share attributable to common stockholders -		
basic and diluted	17,586,210	8,015,687
Other comprehensive loss:		
Net loss	(12,974,799)	(21,121,885)
Unrealized gain (loss) on foreign currency translation	14,353	(86,584)
Total comprehensive loss	(12,960,446)	(21,208,469)
Comprehensive loss attributable to non-controlling interest	(400,847)	(826,629)
Comprehensive loss	$ (12,559,599)	$ (20,381,840)

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Stockholders' Equity

	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Non-Controlling Interest	Total Stockholders Equity
Balance at December 31, 2014	$ 982	$ 35,894,823	$ (24,135,447)	$ —	$ (729,171)	$ 11,031,187
Public offering, 1,886,000 shares, net of underwriters discounts	377	11,400,493	—	—	—	11,400,870
Stock issuance costs	—	(302,460)	—	—	—	(302,460)
Cashless exercise of options, 6812 shares	—	—	—	—	—	—
Stock-based compensation	7	1,573,595	—	—	—	1,573,602
Other comprehensive gain (loss)	—	—	—	(86,584)	—	(86,584)
Net loss	—	—	(20,295,256)	—	(826,629)	(21,121,885)
Balance at December 31, 2015	$ 1,366	$ 48,566,451	$ (44,430,703)	$ (86,584)	$ (1,555,800)	$ 2,494,730
Public offering, 9,100,000 shares, net of underwriters discounts	1,820	6,285,430	—	—	—	6,287,250
Exercise of warrants, 3,863,429 shares	773	3,862,656	—	—	—	3,863,429
Issuance of common stock, 4,791,377 shares	958	7,081,568	—	—	—	7,082,526
Stock issuance costs	—	(510,185)	—	—	—	(510,185)
Stock-based compensation	9	582,621	—	—	—	582,630
Other comprehensive gain (loss)	—	—	—	14,353	—	14,353
Net loss	—	—	(12,573,952)	—	(400,847)	(12,974,799)
Balance at December 31, 2016	$ 4,926	$ 65,868,541	$ (57,004,655)	$ (72,231)	$ (1,956,647)	$ 6,839,934

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
Consolidated Statements of Cash Flows

	For the year ended December 31,	
	2016	**2015**
Cash Flows from Operating Activities		
Net loss	$ (12,974,799)	$ (21,121,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	132,077	115,307
Amortization of deferred financing costs and debt issuance costs	218,827	101,563
Amortization of held to maturity investment premium	32,733	142,442
Stock based compensation	582,630	1,573,602
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	(82,440)	—
Prepaid expenses, restricted cash, and other current assets	532,872	(32,088)
Deposits	—	(50,000)
Related party receivable	(45,000)	(9,375)
Accounts payable	(1,690,048)	642,332
Accrued expenses and other liabilities	(542,255)	1,040,939
Other long term liabilities	311,686	149,748
Net Cash Used in Operating Activities	(13,523,717)	(17,447,415)
Cash Flows from Investing Activities		
Proceeds from maturities of short-term investments	6,656,910	14,956,988
Purchases of short term investments	—	(11,090,091)
Purchase of property and equipment	(45,936)	(115,506)
Net Cash Provided by Investing Activities	6,610,974	3,751,391
Cash Flows from Financing Activities		
Proceeds from public offering, net of underwriting discounts	6,287,250	11,400,870
Proceeds from the issuance of common stock, net of commissions	7,082,526	—
Proceeds from the exercise of warrants	3,863,429	—
Stock issuance costs	(488,585)	(302,460)
Proceeds from issuance of long term debt, net	—	4,470,975
Payments on long term debt	(6,941,821)	(558,179)
Net Cash Provided by Financing Activities	9,802,799	15,011,206
Effect of exchange rate changes on cash and cash equivalents	12,656	(89,531)
Net Increase in Cash and Cash Equivalents	2,902,712	1,225,651
Cash and Cash Equivalents - Beginning of Period	4,939,955	3,714,304
Cash and Cash Equivalents - End of Period	$ 7,842,667	$ 4,939,955
Supplemental Disclosure for Cash Flow Information		
Interest paid	$ 330,576	$ 262,066
Supplemental Schedule of Noncash Investing and Financing Activities		
Cashless exercise of stock options	$ —	$ 32,588

See Notes to Consolidated Financial Statements

1. Organization

Heat Biologics, Inc. ("Heat" or "the Company") was incorporated in 2008 pursuant to the laws of the state of Delaware. Heat is an immuno-oncology company focused on developing novel allogeneic, "off-the-shelf" T cell-activating platform technologies to combat a wide range of cancers and infectious diseases. The Company currently has two drug candidates, one in a Phase 2 trial for non-muscle invasive bladder cancer (NMIBC), and one in a Phase 1b trial for non-small cell lung cancer (NSCLC). We believe the use of these technologies in combination with other immunotherapies has the potential to dramatically improve patient outcomes.

Heat owns 92.5% interest in its subsidiary, Heat Biologics I, Inc. On May 30, 2012, Heat formed two-wholly owned subsidiaries, Heat Biologics III, Inc. ("Heat III") and Heat Biologics, IV, Inc. ("Heat IV"). Heat formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012. Heat also formed Heat Biologics Australia Pty LTD, a wholly-owned proprietary company, registered in Australia on March 14, 2014. On October 25, 2016, Heat formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, dengue and yellow fever.

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

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has an accumulated deficit of approximately $57 million as of December 31, 2016 and a net loss of approximately $12.9 million for the year ended December 31, 2016, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the audited financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings (including through the "at-the-market" Issuance Sales Agreement (the "FBR Sales Agreement") that it entered into with FBR Capital Markets & Co. ("FBR") in August 2016, revised February 2017, and debt financings, partnerships, collaborations and other funding transactions. There can be no assurance that the Company will be able to meet the requirements for use of the FBR Sales Agreement or to complete any such transactions on acceptable terms or otherwise. On April 1, 2016, the Company implemented a cost-savings plan and focused corporate strategy involving reductions in headcount as well as a deferral of a portion of annual base salaries for the Company's leadership team to decrease operating costs. In September 2016, deferred salaries were reimbursed in full. These cost-saving measures are intended to significantly reduce the Company's cost structure and scale the organization appropriately for its current goals. The Company has, and plans to continue to direct its resources primarily to continue to monitor all patients enrolled in its Phase 2 clinical trial of HS-410 for the treatment of NMIBC for the next 12 months and to advance the Phase 1b trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of NSCLC. If the Company is unable to obtain the necessary capital required to maintain operations, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

Principles of Consolidation

The consolidated financial statements include the accounts of Heat Biologics, Inc. and its subsidiaries, Heat Biologics I, Inc. ("Heat I") Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd, and Zolovax, Inc. The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency of the foreign entities. Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders' equity. All significant intercompany accounts and transactions have been eliminated in consolidation. At December 31, 2016 and 2015, 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 interest as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss – non-controlling interest" in the consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used for, but not limited to, useful lives of fixed assets, income taxes and stock-based compensation. Actual results may differ from those estimates.

Cash and Cash Equivalents and Restricted Cash

The Company considers all cash and other highly liquid investments with initial maturities from the date of purchase of three months or less to be cash and cash equivalents. The Company had a restricted cash balance of $101,171 and $101,151 at December 31, 2016 and 2015, respectively. 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 required a minimum $100,000 cash balance to be maintained with the lending bank to secure the Company credit card during 2016 and 2015.

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. As of December 31, 2016 and 2015, cash amounts in excess of $250,000 were not fully insured. The uninsured cash balance as of December 31, 2016 was $7,596,414. The Company does not believe it is exposed to significant credit risk on cash and cash equivalents.

Deferred Financing Costs

Deferred financing costs include the costs incurred to obtain financing and are amortized using the straight-line method, which approximates the effective interest method, over the life of the related debt. Deferred financing 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. Depreciation is calculated using the straight-line method and is based on estimated useful lives of five years for lab equipment and computer equipment, and seven years for furniture and fixtures.

Net Loss per Share

Basic net loss per share is computed by dividing net loss 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.

Fair Value of Financial Instruments

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, accounts payable and accrued expenses and other payables approximate fair value due to their short maturities. The carrying value of debt approximates fair value because the interest rate under the obligation approximates 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 does not have any financial instruments that are measured at fair value on a recurring basis. There were no assets or liabilities measured at fair value on a recurring basis as of December 31, 2016 or 2015.

Marketing

Marketing costs related to our clinical trials are expensed as incurred and are included in research and development expense in the consolidated statement of operations and comprehensive loss. Marketing expense totaled $82,644 and $304,038 for the years ended December 31, 2016 and 2015, 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 carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with FASB ASC 740,*Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2016 and 2015, 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 consolidated statements of operations and comprehensive loss. As of December 31, 2016 and 2015, 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 that requires the recognition of compensation expense for costs related to all stock-based payments, including stock options and restricted stock units. 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. The fair value of restricted stock units is estimated based on the closing price of the Company's stock on the date of grant, and for the purposes of expense recognition, the total new number of shares expected to vest is adjusted for estimated forfeitures.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes-Merton option pricing model on the date of grant for stock options and are 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, 2016 and 2015 represents the average time that options are expected to be outstanding based on the average of the vesting term and the contractual term of the option. 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 in 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 of Miami’s ownership in Heat I, for the years ended December 31, 2016 and 2015.

Revenue Recognition

The Company recognizes revenues from research and research and development agreements and license agreements when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenues from contract research arrangements are recognized as costs are incurred. Contract research costs include all direct material costs, supplemental labor costs and fringe benefits.

Revenue associated with nonrefundable upfront license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected period of performance.

For the year ended December 31, 2016 the Company recognized $341,643 in research funding revenue pursuant to its exclusive license agreement with Shattuck Labs, Inc. (“Shattuck”) pursuant to which Shattuck acquired the rights to take over the research and development of certain preclinical assets. This revenue was for research and development services, which include labor and supplies, provided to Shattuck. There was no revenue for the year ended December 31, 2015.

Research and Development

Research and development costs associated with developmental products not yet approved by the FDA as well as costs associated with bringing developmental products into advanced phase clinical trials as incurred. These costs consist primarily of pre-manufacturing and manufacturing drug costs, clinical trial execution, investigator payments, license fees, salaries, stock-based compensation and related personnel costs. Other costs include fees paid to consultants and outside service providers related to the development of the Company’s product candidates and other expenses relating to the design, development, and testing and enhancement of its product candidates.

Impact of Recently Issued Accounting Standards:

In January 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2017-01,*Business Combinations (Topic 805)* to clarify the definition of a business, which is fundamental in the determination of whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses combinations. The updated guidance requires that in order to be considered a business the integrated set of assets and activities acquired must include, at a minimum, an input and process that contribute to the ability to create output. If substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar assets, it is not considered a business, and therefore would not be considered a business combination. The update is effective for fiscal years beginning after December 15, 2018, and interim periods with fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of adopting this guidance on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230)—Restricted Cash*. ASU 2016-18 requires the statement of cash flows to be a reconciliation between beginning and ending cash balances inclusive of restricted cash balances. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and is to be applied using a retrospective transition method to each period presented. The Company does not anticipate ASU 2016-18 to have a material impact to its consolidated financial statements.

In August 2016, FASB issued (ASU) No. 2016-15, *Statement of Cash Flows* (Topic 230). The guidance is intended to reduce diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The effective date for the standard for public entities is for fiscal years beginning after December 15, 2017. Early adoption is permitted, provided all amendments are adopted in the same period. The guidance requires application using a retrospective transition method. The Company does not anticipate ASU 2016-15 to have a material impact to its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718)* - Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax benefit or expense in the reporting period in which they occur (previously such amounts were recognized in additional paid-in capital); 2) excess tax benefits will be classified as an operating activity in the statement of cash flows; and 3) the option to elect to estimate forfeitures or account for them when they occur. ASU 2016-09 is effective for the Company beginning in the first quarter of 2017. Upon adoption of ASU 2016-09, the Company plans to account for forfeitures as incurred and expects this adoption along with the retrospective impact on its classification of cash flows between operating and financing activities to be immaterial. The Company believes the impact of recording excess tax benefits in income taxes in its consolidated statement of earnings may be material. The magnitude of such impact is dependent upon the Company's future stock price in relation to the fair value of awards on grant date and the Company's future grants of stock-based compensation.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). This ASU issued guidance to simplify the accounting for share-based payments. This new guidance (1) eliminates the ability to recognize excess tax benefits and certain tax deficiencies in additional paid in capital ("APIC") and requires all such items be recognized as income tax expense or benefit; (2) eliminates the presentation of excess tax benefits in the financing section of the statement of cash flows and instead requires such items be recognized in the operating activities section of the statement. This ASU is effective for fiscal years beginning after December 15, 2016, and for interim periods within those annual periods. The Company does not expect the immediate recognition of income taxes under this standard to have a material impact on its statements of operations as it has recorded a full valuation allowance on all deferred tax assets. The Company is currently evaluating the impact of the remainder of this guidance on its financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, requiring lessees to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and (2) a right-of-use ("ROU") asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The update is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The Company currently anticipates that upon adoption of the new standard, ROU assets and lease liabilities will be recognized in amounts that will be immaterial to the consolidated balance sheets.

In January 2016, the FASB issued ASU No. 2016-01,*Recognition and Measurement of Financial Assets and Financial Liabilities (ASU 2016-01).* ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company does not expect the adoption of this guidance will have a material impact on our consolidated financial statements or related footnote disclosures.

In April 2015, the FASB issued ASU No. 2015-03,*Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs (ASU 2015-03)* ASU 2015-03 revises Subtopic 835-30 to require that debt issuance costs be reported in the balance sheet as a direct deduction from the face amount of the related liability, consistent with the presentation of debt discounts. Prior to the amendments, debt issuance costs were presented as a deferred charge (i.e., an asset) on the balance sheet. The ASU provides examples illustrating the balance sheet presentation of notes net of their related discounts and debt issuance costs. Further, the amendments require the amortization of debt issuance costs to be reported as interest expense. Similarly, debt issuance costs and any discount or premium are considered in the aggregate when determining the effective interest rate on the debt. The amendments are effective for public business entities for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The adoption of ASU 2015-03 on January 1, 2016 resulted in the reclassification of $22,707 from non-current assets to an offset to long-term debt as of December 31, 2015. There was no debt at December 31, 2016.

In August 2014, FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40): *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). The amendments in ASU 2014-15 are intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The pronouncement is effective for annual periods ending after December 15, 2016 with early adoption permitted. The Company adopted this standard in 2016. The impact of the adoption of the standard is included in Note 2 to the Company's consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09,*Revenue from Contracts with Customers (ASU 2014-09),* which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. With the deferral, the new standard is effective for the Company on January 1, 2018, with early adoption permitted one year prior. The standard permits the use of either the retrospective or cumulative effect transition method. Due to limited sales, the Company has evaluated its contracts and has concluded that the impact of adopting the standard will have no material impact on its consolidated financial statements and related disclosures

3. Investments

Investments in certain securities may be classified into three categories:

- *Held-to-maturity* - Debt securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost.

- *Trading securities* - Debt and equity securities that are bought and held principally for the purpose of selling in the near term are reported at fair value with unrealized gains and losses included in earnings.

- *Available-for-sale* - Debt and equity securities not classified as either securities held-to-maturity or trading securities are reported at fair value with unrealized gains or losses excluded from earnings and reported as a separate component of stockholders' equity.

The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period. The Company has determined that its debt securities should be classified as held-to-maturity as of December 31, 2015. There were no investments as of December 31, 2016. This classification was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as all of the investments mature within 6 months and the underlying cash invested in these securities is not required for current operations.

Investments consist of short-term FDIC insured certificates of deposit, commercial paper rated A1/P1 or above and corporate notes and bonds rated A and above carried at amortized cost using the effective interest method.

The following summarizes information about short-term investments at December 31, 2016 and 2015:

	Amortized Cost	Gross Unrealized Losses	Estimated Fair Value
2016			
Certificates of deposit, commercial paper	$ —	$ —	$ —
2015			
Certificates of deposit, commercial paper	$ 6,689,643	$ 4,948	$ 6,684,695

As of December 31, 2015, the estimated fair value of the investments was less than the amortized cost. Because management intended to hold the investments until their maturity dates, these unrealized losses were not recorded in the consolidated financial statements.

The maturities of held-to-maturity investments at December 31, 2016 and 2015, respectively were as follows (in thousands):

	Less than 1 Year	Total
2016		
Certificates of deposit, commercial paper	$ —	$ —
2015		
Certificates of deposit, commercial paper	$ 6,689,643	$ 6,689,643

4. Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over estimated useful lives ranging generally from five to seven years. Expenditures for maintenance and repairs are charged to expense as incurred.

Property and equipment consisted of the following at:

	December 31, 2016	December 31, 2015
Lab equipment	$ 587,366	$ 541,065
Computers	38,903	40,545
Furniture and fixtures	55,883	55,883
Total	682,152	637,493
Accumulated depreciation	(322,560)	(191,760)
Property and equipment, net	$ 359,592	$ 445,733

Depreciation expense totaled $132,077 and $115,307 for the years ended December 31, 2016 and 2015, respectively.

5. Accrued Expenses

Accrued expenses consist of the following at:

	December 31, 2016	December 31, 2015
Accrued clinical trial expenses	$ 580,218	$ 1,192,936
Compensation and related benefits	642,532	561,082
Deferred rent	42,423	52,889
Patent fees	40,000	40,000
	$ 1,305,173	$ 1,846,907

6. Debt Issuance Costs

During 2014, the Company recorded $323,021 to debt discount for the initial fair value of the warrant to purchase common stock and $27,500 to deferred financing costs related to third party fees paid in connection to the Square 1 Bank loan, which were being amortized over the 42 month term of the loan. The Company paid the loan off in its entirety in December 2016 and the remaining balance of the debt discount and deferred financing costs were recognized at that time.

Total amortization expense for the debt issuance costs was $218,827 and $101,563 during fiscal year 2016 and 2015, respectively.

7. Notes Payable

In August 2014, the Company entered into a secured loan with Square 1 Bank ("Loan"). The Loan provided the Company with a term loan in the aggregate principal amount not to exceed $7.5 million to be used to supplement working capital. The Loan was available to the Company in four tranches: $1.5 million was made available to the Company on August 22, 2014 ("Tranche 1 Loan"), $1.5 million became available to the Company upon enrollment of the first patient in its the Phase 2 clinical trial for HS-110 ("Tranche 2 Loan"), $2.25 million was made available to the Company upon the initiation of the Phase 1B trial for lung cancer indication on June 30, 2015 ("Tranche 3 Loan"), and $2.25 million was made available to the Company upon Square 1 Bank's receipt on December 30, 2015 of the full enrollment of our Phase 1/2 clinical trial for HS-410 ("Tranche 4 Loan"). As of December 31, 2015, the Company had drawn down the entire $7.5 million available under the Loan. In December 2016, the Company paid the loan in full and it was terminated.

The Loan accrued interest monthly at an interest rate of 3.05% plus the prime rate or 6.30% per annum, whichever was greater. During the year ended December 31, 2015, the Company made $0.6 million in principal payments and $0.3 million in interest payments on the outstanding loan. During the year ended December 31, 2016, the Company made approximately $6.8 million in principal payments, net of discount.

In connection with the Loan, in August 2014, the Company issued Square 1 Bank a warrant exercisable for 52,695 shares of the Company's common stock at an exercise price of $4.27. In accordance with ASC 480-10, *Distinguishing Liabilities from Equity*, the freestanding warrant for the Company's common stock was recognized as a liability and recorded at fair value in all periods prior to exercise. The warrant liability was re-measured to fair value prior to reclassification to additional paid in capital upon its exercise. In September 2014, the warrant was exercised via a cashless exercise into 17,664 shares of the Company's common stock. The initial fair value of the warrant of $0.3 million was recorded as a liability and a discount to notes payable and was amortized to interest expense over the term of the Loan. The debt discount was $0.2 million as of December 31, 2015 and the remaining balance was expensed at the time the Company paid off the loan balance in December 2016.

8. License Agreements

- *University of Miami*

  - Beginning in 2008, the Company has entered into various agreements with the University of Miami (the"University") for intellectual and tangible property rights relating to the *ImPACT*®, technology activities ("License Agreement 03-31, 05-39" and "License Agreement 97-14", or collectively "License Agreements"). These license agreements were subsequently assigned to the Company's subsidiary Heat Biologics I, Inc. (Heat I) which issued to the University shares of its common stock representing seven and one half percent (7.5%) of its common stock. The term of the license is the length of the last to expire patent, unless terminated earlier.

  - The Company agreed to make minimum royalty payments of $10,000 for three years beginning in 2010 that are due on the anniversary date of the agreement for License Agreement 97-14. Beginning in 2013, and thereafter for the life of the agreement, the minimum royalty payment shall be $20,000 due on the same date. In July 2016, the Company and the University entered into an amendment replacing the milestone payment of $250,000 by the earlier of May 31, 2017 or approval of a BLA for the lung cancer vaccine with a payment of $500,000 upon approval of an NDA for a lung cancer vaccine covered by Patent Rights.

  - 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.

  - 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 SS114A, 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 143, 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 J110, 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. There are no financial obligations on our part under the arrangement.

  - In addition, Heat entered into an agreement for"Modified Heat Shock Proteins-Antigenic Peptide Complex" with the University of Miami in September 2014 for a cancer cell line where the University agreed not to license the cell line to third parties while the Company is in good standing and in compliance of its patent license agreements with the University relating to our *ImPACT*® platform. There is no financial obligation on the Company's part under the arrangement.

  - On October 25, 2016, the Company entered into an exclusive license agreement with the University of Miami for the license and development of intellectual property related to its gp96 platform to target the Zika virus and other infectious diseases. As consideration for the rights granted in this license agreement the Company is obligated to pay the University an upfront license fee of $20,000 and nominal annual maintenance fees over the initial ten years that total $82,000 and increasing thereafter. The Company is obligated to pay royalties equal to a percentage (mid-single digits) of net sales of products covered by the patent-relayed rights, subject to reduction if additional licenses from third parties are required to commercialize licensed products.

- *Other License Agreements*

  - 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, Heat agreed to pay the not-for-profit corporation a fee of $5,000 and $50,000, respectively. Heat has the option to renew the license once the original term has expired. Milestone payments are due upon certain events agreed upon by Heat and the not-for-profit corporation. In December 2015, Heat amended the evaluation and biological material license agreement to add additional cell lines in exchange for a one-time payment of $1,000.

  - On August 30, 2010, Heat entered into an option agreement with the University of Michigan ("University II") to acquire the right to negotiate an exclusive license for certain materials which include cancer 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.

  - On September 23, 2014, Heat entered into an exclusive license agreement for a multiple myeloma cell line with Professor Kenneth Nilsson in Sweden. In consideration of the commercial license, Heat agreed to pay an up-front license fee of $5,000 and is obligated to pay an annual maintenance fee of $3,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to $30,000. Milestone payments are due upon certain events agreed upon by Heat and Professor Kenneth Nilsson.

  - In August 2015, the Company entered into an exclusive license agreement with Columbia University for an endometrial cancer cell line for the production, sale and use for all human healthcare applications. The term of the license is perpetual, unless terminated earlier by us or by Columbia University. Columbia University can only terminate for our material breach of this agreement. The Company paid an up-front license fee of $7,500 and is obligated to pay an annual maintenance fee of $5,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to $50,000. The Company agreed to pay royalties equal to a one-tenth of low single digit percentage of net sales of licensed products. In addition, the Company is obligated to make milestone payments of $25,000, $40,000 and $75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial, respectively, $200,000 upon the first commercial sale of a licensed product and $500,000 upon annual net sales of $100,000,000 or more.

  - In June 2016, the Company entered into an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which the Company licensed certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by us. For a six month period, the Company received a monthly fee from Shattuck for supplying certain labor to Shattuck and reimbursement for certain supplies. In addition, the Company has signed a sublease with Shattuck to use a portion of its office and lab space. Shattuck paid the Company an initial license fee of $50,000 and is obligated to pay the Company fees upon its receipt of sublicensing income, achievement of certain milestones and royalties upon sales of commercial products. Inasmuch as the technology that the Company out-licensed is in the early stages of development and there is a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that we will derive any revenue from Shattuck.

Future minimum royalty payments as of December 31, 2016 are as follows (in thousands):

Year ended December 31,	
2017	91
2018	61
2019	30
2020	57
2021	32
Total	$ 271

9. Stockholders' Equity

Authorized Capital

Heat has authorized 10,000,000 shares of Preferred Stock (par value $0.0001) as of December 31, 2016 and 2015. As of December 31, 2016 and 2015, there were no outstanding shares of Preferred Stock.

Heat had 50,000,000 shares of common stock (par value $0.0002) authorized as of December 31, 2016 and 2015. Of the 50,000,000 common stock shares 26,204,39[illegible] and 8,424,641 were issued and outstanding as of December 31, 2016 and 2015, respectively.

Preferred Stock

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; and (iii) 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. As a result of the IPO, all outstanding shares of preferred stock were automatically converted 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 A Preferred Stock was its Original Issue Price ($2.10 for each share of the Series A Preferred Stock) 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 was 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 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 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 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 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. As a result of the IPO, all outstanding shares of preferred stock were automatically converted to common stock.

The preferred stock was determined to have characteristics more akin to equity than debt. Particularly, the preferred stock had no mandatory redemption provision nor was 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 did not need to be bifurcated and classified as a liability.

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 and B Preferred Stock the dividends that would have been declared with respect to common stock issuable upon conversion of the Series A 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 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 an amount per share equal to $4.83 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.

Financings

On August 15, 2016, Heat Biologics, Inc. (the "Company") and FBR Capital Markets & Co. ("FBR") entered into an At Market Issuance Sales Agreement (the "FBR Sales Agreement") pursuant to which the Company may sell from time to time, at its option, shares of its common stock, par value $0.0002 per share, having an aggregate offering price of up to $10.5 million through FBR, as sales agent. The Company may sell shares of its common stock through FBR by any method permitted that is deemed an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through the NASDAQ Capital Market, the existing trading market for the Company's common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Sales of shares of common stock are made pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-199274) filed with the U.S. Securities and Exchange Commission ("SEC"), the base prospectus, dated October 23, 2014, filed as part of such registration statement and the prospectus supplement, dated August 15, 2016. FBR is entitled to compensation at a fixed commission rate up to 3.0% of the gross proceeds per share sold through it as sales agent under the sales agreement. Beginning in August 2016 and through December 31, 2016, the Company sold 4,791,377 shares of common stock under the FBR Sales Agreement resulting in net proceeds of approximately $6.8 million, after FBR's commission and other expenses of $0.3 million.

On March 23, 2016, the Company closed the issuance and sale of 9,100,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 6,825,000 shares of its common stock, at a combined public offering price of $0.75 per share and related warrant (the "Offering"). The warrants are exercisable immediately upon issuance, expire five years after the date of issuance and have an exercise price of $1.00 per share. The net proceeds to the Company from the Offering excluding exercise of warrants, were approximately $6.1 million after deducting underwriting discounts, commissions, and other third party offering expenses. For the year ended December 31, 2016, the Company has raised approximately $3.9 million from the exercise of 3,863,429 warrants. In connection with the Offering, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Roth Capital Partners, LLC and Aegis Capital Corp., as representatives (the "Representatives") of the several underwriters (collectively, the "Underwriters"). The Underwriting Agreement contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions.

On March 10, 2015, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Aegis Capital Corp. ("Aegis"), as representative of the several underwriters named therein (the "Underwriters"), providing for the offer and sale in a firm commitment underwritten public offering (the "Offering") of 1,640,000 shares of the Company's common stock, and 246,000 additional shares of the common stock to cover over-allotments at an offering price of $6.50 per share. The net proceeds to the Company from the Offering were approximately $11.1 million, after deducting underwriting discounts, commissions, and other third party offering expenses. The Underwriting Agreement contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions.

Restricted Stock

On December 30, 2016 the Company granted 75,000 restricted stock units to the Chief Executive Officer in which25%, (18,750 restricted stock units) vested immediately and the remainder will vest on each anniversary of the grant date over a three year period. Additionally, the Company issued 5,000 shares to one of its employees during the year ended December 31, 2016. The Company recognized $24,278 in stock-based compensation expense for employees related to restricted stock awards during the year ended December 31, 2016. There was no restricted share expense for employees prior to this period.

The Company recognized stock-based compensation related to issuance of restricted stock to nonemployees in exchange for services totaling $27,996 and $78,815 for the years ended December 31, 2016 and 20015, respectively.

Common Stock Warrants

In connection with the March 23, 2016 public offering, the Company issued 9,100,000 shares of common stock and warrants to purchase 6,825,000 shares of common stock. Each share of common stock was sold together with a warrant to purchase 0.75 of a share of common stock. The warrants have an exercise price of $1.00 per share and expire five years from the issuance date. These warrants do not meet the criteria required to be classified as liability awards and therefore the Companyconcluded that the warrants are considered equity instruments. The fair value of the common stock warrants as of the issuance date was approximately $2,522,754. As of December 31, 2016, warrants for 3,863,429 shares of common stock issuable at $1.00 per share have been exercised and 2,961,571 are outstanding.

	Common Stock Warrants
Outstanding, December 31, 2014	142,392
Outstanding, December 31, 2015	142,392
March 23, 2016 public offering	6,825,000
Exercised	(3,863,429)
Expired	—
Outstanding, December 31, 2016	3,103,963

In connection with our July 23, 2013 initial public offering, the Company issued warrants to the underwriters for 125,000 shares of common stock issuable at $12.50 per share upon exercise. The warrants expire five years from the issuance date.

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. In February 2014, 15,218 warrants were exercised in cashless transactions that resulted in the issuance of 14,318 shares of common stock and 17,392 are outstanding.

The Company has a total of 3,103,963 warrants outstanding at a weighted average exercise price of $1.46 to purchase its common stock as of December 31, 2016. These warrants are summarized as follows:

Issuance Date	Number of Shares	Exercise Price	Expiration Date
3/10/2011	17,392	$ 0.48	3/10/2021
7/23/2013	125,000	$12.50	7/23/2018
3/23/2016	2,961,571	$ 1.00	3/23/2021

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. The Company amended the 2009 Plan to increase the number of shares available for issuance to 869,565. As of December 31, 2016 and 2015, there were 249,767 and 553,105 stock options outstanding under the 2009 Plan, respectively.

2014 Stock Incentive Plan

In June 2014, the stockholders approved the 2014 Stock Option Plan of Heat Biologics, Inc. (the "2014 Plan"), under which the Company is authorized to grant 500,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2014 Plan. In 2015, the stockholders approved an amendment to the Plan to increase the number of shares by 600,000 that would allow the Company to grant up to 1,100,000 awards, as amended. Persons eligible to participate in the 2014 Plan include employees, directors, and consultants. Stock options granted under the 2014 Plan generally have terms of 10 years and have various vesting schedules. As of December 31, 2016 and 2015, there were 886,986 and 661,581 stock options outstanding under the 2014 Plan, respectively.

As of December 31, 2016, there are 2,242,534 stock options remaining available for grant under the Plans. The following table summarizes the components of the Company's stock-based compensation included in net loss:

	For the years ended December 31,	
	2016	2015
Employee stock options	$ 527,697	$ 924,343
Non-employee stock options	2,664	570,445
Employee stock awards	24,276	—
Non-employee stock awards	27,993	78,814
	$ 582,630	$ 1,573,602

Stock Options

The fair value of each stock option is estimated on the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions for stock options granted during the years ended:

	December 31,	
	2016	2015
Dividend yield	0.0%	0.0%
Expected volatility	72.95-78.54%	72.4-107.6%
Risk-free interest rate	1.36-2.25%	1.69-2.27%
Expected term (years)	5.4 - 6.3	6.25 – 10

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 had limited to no 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 estimate the expected term. 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. As required by ASC 718, the Company reviews recent forfeitures and stock compensation expense. Additionally, the Company conducts a sensitivity analysis. Based on these evaluations the Company currently does not apply a forfeiture rate.

The Company recognized $530,361 and $1,494,788 in stock-based compensation expense for the years ended December 31, 2016 and 2015, respectively, for the Company's stock option awards.

The following tables summarize the stock option activity for the year ended December 31, 2016:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,214,686	$ 4.93
Granted	531,339	$ 1.99
Exercised	—	$ —
Forfeited/Expired	(609,272)	$ 4.23
Outstanding, December 31, 2016	1,136,753	$ 3.93

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2016 and 2015 was $1.29 and $3.20, respectively.

The total fair value of stock options that vested during the year ended December 31, 2016 was approximately $4,636,660.

The following table summarizes information about stock options outstanding at December 31, 2016:

Options Outstanding			Options Vested and Exercisable		
Balance as of 12/31/2016	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Balance as of 12/31/2016	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
1,136,753	7.8	$3.93	699,334	7.0	$4.76

As of December 31, 2016, the unrecognized stock-based compensation expense related to unvested stock options was approximately $2.0 million that is expected to be recognized over a weighted average period of approximately 21.2 months.

Total stock-based compensation expense including restricted stock, stock options, and common stock was $582,630 and $1,573,602 for the years ended December 31, 2016 and 2015, respectively.

10. Income Tax

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

	Years ended December 31,	
	2016	2015
Current expense:		
Federal	$ —	$ —
State	—	—
Deferred expense (benefit):		
Federal	$ —	$ —
State	—	—
Total	$ —	$ —

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:

	Years ended December 31,	
	2016	2015
Federal income tax expense at statutory rate	$ (4,411,000)	$ (7,182,000)
Increase (reduction) in income tax resulting from:		
State and local income taxes, net of federal benefit	69,000	(420,000)
Foreign rate differential	(18,000)	64,000
Non-deductible expenses	8,000	—
Prior-period true-up	547,000	(489,000)
Research & development credit	(575,000)	(171,000)
Stock-based compensation	113,000	194,000
Other	(1,000)	—
Increase in valuation allowance	4,268,000	8,004,000
	$ —	$ —

The tax effects of temporary differences and operating loss carryforwards that give rise to significant portions of the deferred tax assets and deferred tax liabilities are presented below:

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforward	$ 19,303,020	$ 15,758,242
Research & development credit	1,557,475	982,429
Stock-based compensation	838,297	791,109
Other	203,661	100,126
Deferred tax assets	21,902,453	17,631,906
Deferred tax liabilities:		
Property, plant and equipment, primarily due to differences in depreciation	(41,953)	(39,758)
Deferred tax liabilities:	(41,953)	(39,758)
Valuation allowance	(21,860,500)	(17,592,148)
Net deferred income taxes	$ —	$ —

At December 31, 2016 and December 31, 2015, the Company evaluated all significant available positive and negative evidence, including the existence of losses in recent years and management's forecast of future taxable income, and, as a result, determined it was more likely than not that federal and state deferred tax assets, including benefits related to net operating loss carryforwards, would not be realized. The valuation allowance was increased from $17,592,148 at December 31, 2015 to $21,860,500 at December 31, 2016. The increase in valuation allowance was due primarily to the increase in net operating loss carryforwards.

At December 31, 2016, the Company has federal net operating loss carryforwards of $53,306,736, which are available to offset future taxable income. The federal net operating loss carryforwards begin to expire in 2029. The Company has various state net operating loss carryforwards totaling $48,370,787, which are available to offset future state taxable income. State net operating losses begin to expire in 2024. The Company has various foreign net operating loss carryforwards of $721,519. The foreign net operating loss carryforwards are carried forward indefinitely. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, state, and foreign income tax authorities.

In accordance with FASB ASC 740,*Accounting for Income Taxes*, the Company reflects in the consolidated 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, 2016 and 2015, 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 operations. As of December 31, 2016 and 2015, the Company had no such accruals.

The Company files income tax returns in the United States and various state and foreign jurisdictions. The Company is subject to examination by taxing authorities for the tax years ended December 31, 2008 through 2015.

Potential 382 Limitation

The Company's ability to utilize its net operating loss (NOL) and research and development (R&D) credit carryforwards may be substantially limited due to ownership changes that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change," as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups.

The Company has not completed a study to assess whether one or more ownership changes have occurred since the Company became a loss corporation under the definition of Section 382. If the Company has experienced an ownership change, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any such limitation may result in the expiration of a portion of the NOL or R&D credit carryforwards before utilization. Until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit under ASC-740. Any carryforwards that expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, it is not expected that any possible limitation will have an impact on the results of operations of the Company.

11. Related Party Transactions

The Company compensates its board members. Board members received between approximately $61,000 and $118,000 and $40,000 and $43,750 for services rendered during 2016 and 2015, respectively.

The Company had a related party payable balance of $0 as of December 31, 2016 and 2015.

The Company had a related party receivable balance of $103,017 and $58,017 as of December 31, 2016 and 2015, respectively. This related party receivable reflects a percent of labor that the Company's former Chief Scientific Officer, Dr. Schreiber performed on behalf of the Company's former subsidiary Pelican, Inc. Subsequent to year end, the Company entered into an agreement to purchase 80% of the outstanding stock of Pelican, Inc. on a fully diluted basis.

12. Net Loss Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders 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 and warrants that are computed using the treasury stock method.

For the years ended December 31, 2016 and 2015, all of the Company's common stock options and warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

The following table reconciles net loss to net loss attributable to Heat Biologics, Inc.:

	For the years ended December 31,	
	2016	2015
Net loss	$ (12,974,799)	$ (21,121,885)
Net loss - Non-controlling interest	(400,847)	(826,629)
Net loss attributable to Heat Biologics, Inc.	$ (12,573,952)	$ (20,295,256)
Weighted-average number of common shares used in net loss per share attributable to common stockholders —basic and diluted	17,586,210	8,015,687
Net loss per share attributable to Heat Biologics, Inc —basic and diluted	$ (0.71)	$ (2.53)

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

	For the years ended December 31,	
	2016	2015
Outstanding stock options	1,136,753	1,214,686
Unvested restricted stock units	56,250	—
Outstanding common stock warrants	3,103,963	142,392

13. Commitments and Contingencies

On January 24, 2014 the Company entered into a five-year lease for 5,303 square feet of office and laboratory space for monthly rent of $10,341 exclusive of payments required for maintenance of common areas and utilities. On September 30, 2014 the lease was amended to expand the premises by an additional 676 square feet for a total of 5,979 square feet at a monthly rent of $11,638. The Company believes that such facilities are adequate for our current operations, and that there are spaces available sufficient for any future expansion requirements should the need arise. Rent expense was $259,050 and $175,685, for the years ended December 31, 2016 and 2015, respectively. The Company's approximate future minimum payments for its operating lease obligations that have initial remaining non-cancelable terms in excess of one year are as follows (in thousands):

Years ending December 31,	
2017	225,411
2018	232,173
2019	196,727
Thereafter	—
Total	$ 654,311

14. Subsequent Events

On March 7, 2017, Heat Biologics, Inc. ("Heat") entered into a Stock Purchase Agreement (the "Purchase Agreement") with Pelican Therapeutics, Inc. ("Pelican"), and certain stockholders in Pelican (the "Majority Pelican Stockholders") to purchase outstanding capital stock of Pelican (the "Acquisition"). Pelican is a biotechnology company focused on the development and commercialization of monoclonal antibody and fusion protein-based therapies that are designed to activate the immune system. Under the Purchase Agreement, it is a condition to closing that holders of at least 80% of the outstanding capital stock of Pelican on a fully diluted basis participate in the Acquisition. Heat and Pelican intend to provide all Pelican stockholders with the opportunity to participate in the Acquisition by executing Joinder Agreement pursuant to which they will become a party to the Purchase Agreement and agree to sell at least 80% (and up to 100%) of their shares. In order to participate in the Acquisition, Pelican stockholders must return executed Joinder Agreement and other related documents to Pelican by the closing of the transaction, which is currently expected to occur no later than April 30, 2017. The Majority Pelican Stockholders own 75.5% of the fully diluted Pelican shares and have agreed to backstop the Acquisition and sell additional shares of Pelican common stock in the Acquisition (up to 100% of their shares) in order to enable Heat to acquire 80% of the outstanding capital stock of Pelican on a fully diluted basis. As of the date hereof, stockholders of Pelican holding in excess of 80% of the outstanding capital stock of Pelican on a fully diluted basis, which includes the Majority Pelican Stockholders, have entered into Purchase Agreements and agreed to sell up to 100% of their shares in order to enable us to acquire 80% of the outstanding capital stock of Pelican on a fully diluted basis.

On March 15, 2017, Heat Biologics, Inc. (the "Company") received written notice from the Listing Qualifications Department of The NASDAQ Stock Market LLC ("NASDAQ") notifying the Company that for the preceding 30 consecutive business days (January 30, 2017 through March 14, 2017), the Company's common stock did not maintain a minimum closing bid price of $1.00 ("Minimum Bid Price Requirement") per share as required by NASDAQ Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of the Company's common stock and the common stock will continue to trade on The NASDAQ Capital Market under the symbol "HTBX."

In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company has a compliance period of 180 calendar days, or until September 11, 2017, to regain compliance with NASDAQ Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of the Company's stock is at or above $1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case NASDAQ will notify the Company of its compliance and the matter will be closed.

If, however, the Company does not achieve compliance with the Minimum Bid Price Requirement by September 11, 2017, the Company may be eligible for additional time to comply. In order to be eligible for such additional time, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The NASDAQ Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify NASDAQ in writing of its intention to cure the deficiency during the second compliance period.

The Company intends to actively monitor the bid price of its common stock and will consider available options to regain compliance with the NASDAQ listing requirements, including such actions as effecting a reverse stock split to maintain its NASDAQ listing.

On March 28, 2017, the Company closed on an underwritten public offering (the "Offering") of 5,000,000 shares of the Company's common stock, at an offering price of $0.80 per share and on March 30, 2017 issued an additional 750,000 shares in the Offering in connection with the underwriter's exercise of their over-allotment option. The net proceeds to the Company from the Offering were approximately $4.1 million, after deducting underwriting discounts and commissions and estimated Offering expenses payable by the Company. Aegis Capital Corp. ("Aegis") acted as the sole book-running manager for the offering. The Underwriting Agreement with Aegis contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and Aegis, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions. The Underwriting Agreement is filed as Exhibit 1.1 to the Form 8-K filed March 23, 2017.

EXHIBIT 10.67

FIRST AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT
BETWEEN
THE REGENTS OF THE UNIVERSITY OF MICHIGAN
AND
HEAT BIOLOGICS, INC.
(UM FILE NUMBER 3680)

This First Amendment to Exclusive License Agreement (this "First Amendment"), dated December 1, 2016, is by and between Heat Biologics, Inc. ("LICENSEE") and the Regents of the University of Michigan ("MICHIGAN").

WHEREAS, LICENSEE and MICHIGAN entered into an Exclusive License Agreement dated July 22, 2011, (the "Agreement");

WHEREAS, LICENSEE is currently in possession of the Materials;

WHEREAS, LICENSEE previously made an Annual Fee (under Paragraph 3.1(b)(1)) for 2012, 2013, 2014 and 2015 totaled at $40,000;

WHEREAS, LICENSEE previously made a first non-creditable milestone $25,000 payment that MICHIGAN is entitled to retain; and

WHEREAS, LICENSEE and MICHIGAN desire to modify certain provisions of the Agreement as provided herein.

NOW THEREFORE, MICHIGAN and LICENSEE hereby agree as follows:

1. Paragraph 3.1(c)(1) of the Agreement is hereby deleted in its entirety.

2. Paragraph 5.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

   5.2 As part of the diligence required by Paragraph 5.1, LICENSEE agrees to reach the following commercialization and research and development milestones for the LICENSED PRODUCTS and LICENSED PROCESSES (together the "MILESTONES") by the following dates:

   1) Completion of Phase I Clinical Trial on or before January 1, 2020.
   2) Completion of Phase II Clinical Trial on or before January 1, 2022.
   3) Completion of Phase III Clinical Trial on or before January 1, 2024.
   4) FIRST COMMERCIAL SALE on or before January 1, 2025.

3. MICHIGAN agrees that LICENSEE shall not owe MICHIGAN an Annual Fee (under Paragraph 3.1(b)(1)) for 2016 that was otherwise due on July 30, 2016. Furthermore, MICHIGAN agrees that LICENSEE shall not owe MICHIGAN an Annual Fee (under Paragraph 3.1(b)(1)) for 2017, 2018, 2019 and 2020.

4. Each Party each mutually releases the other Party from any breach of the Agreement that may have occurred prior to the date of this First Amendment.

5. Except as specifically modified and amended above, all other terms and conditions of the Agreement remain unchanged and in effect and are hereby ratified and adopted as through fully set forth herein.

IN WITNESS WHEREOF, the parties hereto have entered into this First Amendment to the Agreement as of the date and year first above-written.

FOR LICENSEE

By: /s/ Jeff Wolf
Jeff Wolf
Title: CEO

Date: 12-8-16

FOR THE REGENTS OF THE UNIVERSITY OF MICHIGAN

By: /s/ Kenneth J. Nisbet
Kenneth J. Nisbet
Assoc. Vice President for Research, Tech Transfer
Date: 12-7-16

EXHIBIT 10.68

FIRST AMENDMENT TO THE
STOCK PURCHASE AGREEMENT

This First Amendment to the Stock Purchase Agreement, dated March 29, 2017 (this "***Amendment***"), is made by and among Heat Biologics, Inc., a Delaware corporation ("***Purchaser***"), Pelican Therapeutics, Inc., a Delaware corporation (the "***Company***") and Josiah Hornblower, as representative of the Stockholders (the "***Stockholders' Representative***"). Capitalized terms not defined herein shall have the meanings set forth in the Stock Purchase Agreement, dated as of March 7, 2017 (as amended, modified or supplemented from time to time in accordance with its terms, the "***Purchase Agreement***"), by and among the Purchaser, the Company, the Stockholders party thereto and the Stockholders' Representative.

WHEREAS, pursuant to the Purchase Agreement, the Purchaser has agreed to purchase from the Stockholders, and the Stockholders have agreed to sell, the Purchased Shares, subject to the satisfaction or waiver of certain conditions set forth in the Purchase Agreement; and

WHEREAS, the parties hereto desire to amend the Purchase Agreement in accordance with Section 12.3 thereof, as hereinafter provided.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Amendment. Section 6.13 of the Purchase Agreement is hereby amended and restated in its entirety as follows:

"6.13 CPRIT Agreement. Provided that the Purchaser has made a funding commitment to Pelican in respect of the CPRIT Grant in an amount of not less than $910,231 by the close of business on April 5, 2017, the Company shall have delivered to the Purchaser a fully executed agreement with CPRIT with respect to the CPRIT Grant (the "***CPRIT Agreement***") and the CPRIT Agreement shall be in full force and effect as of the Closing Date and shall not have been amended or modified as of the Closing Date. The funding commitment by CPRIT with respect to the CPRIT Grant under the CPRIT Agreement shall not have been amended, modified or rescinded as of the Closing."

2. Miscellaneous.

a. Effect on the Purchase Agreement. Except as expressly amended or modified by this Amendment, all terms, conditions and covenants contained in the Purchase Agreement remain in full force and effect.

b. Counterparts. This Amendment may be executed by the parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument. Each counterpart may consist of a number of copies hereof each signed by less than all, but together signed by all, of the parties hereto.

c. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to its principles or rules of conflict of laws.

d. Effectiveness of Amendment. This Amendment shall become effective as of the date first set forth above.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first written above.

THE PURCHASER:

HEAT BIOLOGICS, INC.

By /s/ Jeff Wolf
Name: Jeff Wolf
Title: Chief Executive Officer

THE COMPANY:

PELICAN THERAPEUTICS, INC.

By /s/ Josiah Hornblower
Name: Josiah Hornblower
Title: Chief Executive Officer

STOCKHOLDERS' REPRESENTATIVE:

By /s/Josiah Hornblower
Name: Josiah Hornblower
Title: Stockholders' Representative

EXHIBIT 21.1

Subsidiaries

Name of Subsidiary	Jurisdiction
Heat Biologics I, Inc.	Delaware
Heat Biologics III, Inc.	Delaware
Heat Biologics IV, Inc.	Delaware
Heat Biologics GmbH.	Germany
Heat Biologics Australia Pty LTD	Australia
Zolovax, Inc.	Delaware

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Heat Biologics, Inc.
Durham, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-199274 and No. 333-214868) and Form S-8 (No. 333-193453, No. 333-196763, No. 333-207108 and No. 333-213133) of Heat Biologics, Inc. of our report dated March 31, 2017, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 31, 2017

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Wolf, certify that:

1. I have reviewed this annual report on Form 10-K of Heat Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2017

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ann Rosar, certify that:

1. I have reviewed this annual report on Form 10-K of Heat Biologics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2017

By: /s/ Ann Rosar
Name: Ann Rosar
Title: Vice President of Finance
(Principal Financial and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Heat Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2017

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Heat Biologics, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2016 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2017

By: /s/ Ann Rosar
Name: Ann Rosar
Title: Vice President of Finance
(Principal Financial and Principal Accounting Officer)