HEAT BIOLOGICS, INC.
Form 10-K
March 27, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

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.

(Name of small business issuer in its charter)

Delaware	**26-2844103**
(State or other jurisdiction of incorporation or organization)	*(IRS 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	NASDAQ

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 þ

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 þ

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 þ 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 þ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated file, a non-accelerated file, 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	þ
(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 þ

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2014, was approximately $24,626,449 based on $5.55, the price at which the registrant's common stock was last sold on that date.

As of March 27, 2015, the issuer had 8,394,456 shares of common stock outstanding.

Documents incorporated by reference: None.

HEAT BIOLOGICS, INC.

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PART I

Forward-Looking Statements

Certain of the matters discussed within this report include forward-looking statements on our current expectations and projections about future events. In some cases you can identify forward-looking statements by terminology such as may, should, potential, continue, expects, anticipates, intends, plans, believes, estimates, and s 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. Such risks and uncertainties include the risks noted under Item 1A Risk Factors. We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to we, us, our, and Heat Biologics, refer to Heat Biologics, Inc. and its subsidiaries.

Item 1.

Business

Overview

We are a biopharmaceutical company engaged in developing novel allogeneic, off-the-shelf cellular therapeutic vaccines to combat a wide range of cancers and infectious diseases. Our proprietary *ImPACT* - Immune Pan Antigen Cytotoxic Therapy has been designed to deliver live, genetically-modified, irradiated human cells which secrete a broad spectrum of disease-associated antigens together with a potent immune response stimulator called gp96. The secreted antigen-gp96 complexes educate and activate a patient s immune system to recognize and kill diseased cells. In cancer patients our *ImPACT* therapy generates anti-cancer immune responses by mobilizing and activating cytotoxic killer T cells that target multiple cancer antigens, thus harnessing a patient s own immune system to fight cancer.

Unlike autologous or personalized therapeutic vaccine approaches which require extraction and processing of cancer or blood from each individual patient, our *ImPACT* therapeutic vaccines do not require custom manufacturing. Rather our vaccines are made using existing human cell lines which can be mass-produced for immediate use in all patients with the same disease. As such, we believe our off-the-shelf, immunotherapy approach offers logistical, manufacturing and cost of goods benefits compared to one-off autologous patient-specific approaches.

Currently, two of our product candidates, HS-110 and HS-410 are being evaluated in Phase 2 clinical trials for non-small cell lung cancer and bladder cancer, respectively.

HS-110

In the third quarter of 2014, we initiated a Phase 2 clinical trial of our therapeutic vaccine candidate HS-110 (Viagenpumatucel-L) in non-small cell lung cancer (NSCLC) patients. 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. The Phase 2 clinical trial will evaluate HS-110 in combination with low dose cyclophosphamide versus chemotherapy alone in third-line or fourth-line NSCLC patients. The trial will enroll 123 patients at approximately 20 to30 investigative centers and enrollment is expected to be completed during the fourth quarter of 2015.

The inventor of the *ImPACT* technology that we license 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. The results of this Phase 1 trial with HS-110 provides evidence of a CD8-CTL IFN- 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-). 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- 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 pre-clinical published studies on *ImPACT* therapy.

HS-410

In October 2014, we initiated a Phase 2 clinical trial of our therapeutic vaccine candidate HS-410 (Vesigenurtacel-L) in bladder cancer patients. We completed enrollment in the Phase 1 portion of a Phase 1/2 bladder cancer trial with HS-410 in October 2014. HS-410 is a biologic product comprising a bladder cancer cell line genetically modified to secrete a wide range of bladder cancer antigens bound to gp96 molecules and thereby activate a T-cell mediated pan-antigen immune response against the patient s bladder cancer. The Phase 2 trial will 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. The Phase 2 study is evaluating HS-410 in combination with intravesical bacillus Calmette-Guérin (BCG) immunotherapy instillations. We anticipate including approximately 10-15 clinical sites and expect to complete enrollment in the study in the fourth quarter of 2015.

On January 26, 2015, we announced positive data from two patients in the Phase 1 portion of our Phase 1/2 clinical trial of HS-410 in non-muscle invasive bladder cancer (NMIBC). More specifically, analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG (*bacillus Calmette-Guerin*) followed by six weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When the patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. We also reported that with respect to a second patient, a non-specific immune infiltrate was noted on week seven to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. The second patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate. We are still evaluating many patients from our Phase 1 clinical trial of HS-410 in NMIBC and continuing our ongoing Phase 2 clinical study.

On February 26, 2015 we announced we had formed a partnership with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) to accelerate Phase 2 enrollment in NMIBC and to initiate planning for Phase 3 trial.

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 non-muscle invasive bladder cancer. The FDA established the Fast Track Drug Development Program under the FDA Modernization Act of 1997. The 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 development to support approval and eligibility for priority review depending on clinical data at the time of Biologics License Application (BLA) submission.

Additional Indications

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

Product Candidate	Indication	Phase of Development	Upcoming Milestone(s)
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Enrolling patients in Phase 2 trial	2015 Report interim data on immune response throughout the year and complete enrollment in Phase 2
HS-410	Bladder Cancer Adjuvant	Enrolling patients in Phase 2 trial	2015 - Report Phase 1 data on immune response and safety; and complete enrollment in Phase 2

We continue to evaluate other indications for our *ImPACT* therapeutic vaccines and have developed cell lines for ovarian cancer, triple negative breast cancer and pediatric rhabdomyosarcoma. Our decision to further pursue any of 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. As the licensee of the *ImPACT* technology, we have been the beneficiary of over $14M in research funding awarded to the primary inventor of the technology we license by the National Institutes of Health (NIH) and other institutions.

ImPACT Therapy Novel Pan-Antigen Immune Activation

Our *ImPACT* therapy is a novel technology platform designed to educate and stimulate the immune system to combat specific diseases, particularly cancer. *ImPACT* utilizes live attenuated, genetically-modified human cells which secrete gp96 molecules complexed with an array of tumor associated antigens. These secreted gp96-antigen complexes elicit a potent immune response against cancer cells by mobilizing and activating a patient s own tumor-targeting killer T cells. In contrast with other vaccine technologies that target only a single antigen, *ImPACT* *s* pan-antigen approach may potentially provide a more robust and sustained anti-cancer immune response, and limit cancer cells ability to evade the immune system. We believe the clinical and pre-clinical results obtained to date suggest that our *ImPACT* approach generates anti-tumor immune responses capable of attacking tumors. In addition to targeting a wide range of cancers, we believe our novel, off-the-shelf, live cell therapy has the potential to be used against various infectious diseases, such as hepatitis C, malaria and HIV. Encouraging data from non-human primate studies of viral infections have been reported. We have leveraged our existing infrastructure by developing additional product candidates in areas where we can use our proprietary technology. Our success will depend on the clinical and regulatory success of our product candidates and our ability to retain, on commercially reasonable terms, financial and managerial resources, which are currently limited. To date, we have not received regulatory approval for any of our product candidates or derived any revenues from their sales. Moreover, there can be no assurance that we will ever receive

regulatory approval for any of our product candidates or derive any revenues from their sales.

Our Product Candidates and Clinical Development Programs

Our development program involves testing our *ImPACT* -based product candidates against a number of disease targets, including non-small cell lung cancer and bladder cancer. We have begun dosing in our Phase 2 clinical trial protocol for HS-110, our lead drug candidate, in non-small cell lung cancer (NSCLC). Our Phase 2 trial will expand upon the Phase 1 results obtained by the primary inventor as described below. In the third quarter of 2014, we completed the Phase 1 portion and began dosing in the Phase 2 portion of a Phase 1/2 clinical trial in bladder cancer using our HS-410 drug candidate. We plan to utilize this vaccine to delay or prevent the recurrence of bladder cancer in post-resected bladder cancer patients.

Recent Developments

On March 16, 2015, we completed a firm commitment underwritten public offering of 1,886,000 shares of our common stock at a closing price of $6.50 per share for gross proceeds of $12.3 million and net proceeds to us of approximately $11.1 million.

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.

On February 17, 2015, we entered into an agreement with OncoSec Medical Inc. (OncoSec) (OTCQB: ONCS) to jointly evaluate a combination of the immunotherapy approaches developed by each of us in an effort to expand the application of the technologies of both companies to benefit cancer patients. Under the agreement, we will jointly evaluate the preclinical efficacy of our proprietary gp-96-Ig based *ImPACT* immunotherapy platform using OncoSec s core technology, ImmunoPulse, an investigational stage intratumoral DNA delivery platform.

On January 26, 2015, we announced positive data from two patients in the Phase 1 portion of our Phase 1/2 clinical trial of HS-410 in NMIBC. More specifically, analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG (*bacillus Calmette-Guerin*) followed by six weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When the patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. We also reported that with respect to a second patient, a non-specific immune infiltrate was noted on week seven to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. The second patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate. We are still evaluating many patients from our Phase 1 clinical trial of HS-410 in NMIBC and continuing our ongoing Phase 2 clinical study.

Our History

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 801 Capitola Drive, Bay 12, Durham, NC 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 and Nominating 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 and Heat Biologics Australia Pty Ltd.

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 March 14, 2014. We assigned our proprietary rights related to the development and application of our *ImPACT* Therapy for the treatment of non-small lung cancer to Heat Biologics III, Inc. and our proprietary rights related to the development and application of our *ImPACT* Therapy to the treatment of bladder cancer to Heat Biologics IV, Inc. 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, off-the-shelf therapeutic vaccines. We are focused on discovering, developing and applying our core platform *ImPACT* technology towards a number of disease indications. The key elements of our strategy are:

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Develop and obtain regulatory approval for our ImPACT™-based products. We have begun dosing in a Phase 2 clinical trial in NSCLC in the third quarter of 2014 and are currently conducting a Phase 1/2 clinical trial in bladder cancer, the Phase 2 portion of which we initiated in the fourth quarter of 2014. After NSCLC and bladder cancers, depending upon funding and partnering opportunities, we plan to initiate additional clinical trials and in some cases expand current clinical trials against these and other disease targets utilizing our *ImPACT* technology platform.

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Maximize commercial opportunity for our ImPACT™ technology. Our product candidates target large markets with significant unmet medical needs. For each of our product candidates, we seek to retain all manufacturing, marketing and distribution rights which should give us the ability to maximize the economic potential of any future U.S. or international commercialization efforts. We believe that we should be well positioned to successfully commercialize our product candidates independently or through U.S. and international corporate partnerships.

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Enhance our partnering efforts. We are continually exploring partnerships for licensing and other collaborative relationships and remain opportunistic in seeking strategic partnerships.

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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 licensed exclusive rights to five different patent families directed to therapeutic compositions and methods related to our vaccine platform and preclinical development programs. We have recently filed two U.S provisional patent applications relating to our programs. Together, these families comprise 13 issued patents, 3 allowed patent applications, and 42 pending patent applications. These patents and applications cover the United States, Europe, and Japan as well as several other countries that have commercially significant markets.

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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.

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Obtain additional grant funding. To more fully develop our *ImPACT*™ technology platform and its application to a variety of human diseases, we plan to continue to seek and access external sources of grant funding on our own behalf and in conjunction with our academic 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.

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

Disease Targets and Markets

The Oncology Market

The American Cancer Society estimates that 1.66 million people in the U.S. will be diagnosed with cancer in 2015. The lifetime probability of being diagnosed with an invasive cancer is 43% for men and 38% for women. It is projected that 589,430 Americans will die from cancer in 2015.

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 U.S. (22.9%) behind heart disease (23.7%). The American Cancer Society estimates that one in four deaths in the U.S. is due to cancer.

The main treatments for cancer are surgery, radiotherapy and chemotherapy. There are often, however, significant debilitating effects resulting from these treatments or lingering morbidity associated with these approaches to treatment of cancer. Our goal is to develop 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 internally, 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:

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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.

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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.

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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.

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Immune system suppression. A weakened immune system not only inhibits the body's natural ability to fight cancer, but also causes patients to become more susceptible to infections and other diseases. Current approaches to cancer treatment generally involve introduction of an agent, such as a chemical, an antibody or radiation, which causes cell apoptosis (programmed cell death) or inhibits the proliferation of all cells, including immune cells, which has the unintended consequence of indirectly suppressing the immune system.

Immunotherapy Overview

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

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

Therapeutic vaccines, such as *ImPACT* -based product candidates, operate in a fashion similar to *prophylactic vaccines* except that *therapeutic vaccines* are administered after a particular disease is already present. In each case, the human immune system is educated and harnessed to recognize and fight the disease of interest. Cancer can be considered a failure of the immune system to effectively recognize and eliminate inappropriately dividing and multiplying (malignant) cells. Under ordinary circumstances the human immune system continuously monitors and eliminates inappropriately dividing cells. However, for reasons that are not entirely understood, under cancerous conditions the immune system fails to recognize malignant cells and such cells are permitted to inappropriately multiply, grow and metastasize to form tumors which 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. Because immune responses against cancer using vaccines made of the select cancer-associated antigens are often weak, our approach is to complex the cancer-associated antigens with gp96, a powerful antigen-specific adjuvent. The antigen-gp96 complexes induce a much more vigorous anti-cancer immune response than using vaccines comprised of only the cancer-associated antigens themselves.

Immunotherapy Approaches

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

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

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

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

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Most active immunotherapies use normal, non-mutated, self-antigens which are typically poor at stimulating immune responses, even from healthy immune systems. In fact, the human immune system generally does not generate immune responses against self-antigens. Most passive and active immunotherapies also target one or only a few antigens, which increases the probability that infected cells will escape detection by the immune system and immunotherapy.

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Many active immunotherapies employ a single defined antigen so they are not effective against cancers which do not express that antigen.

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Most immunotherapies produce toxic effects resulting in damage to healthy tissues.

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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.

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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.

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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* platform, especially the continual secretion of adjuvant-bound antigens and the pan-antigenic nature of Heat s therapeutic vaccines, combined with a well-honed clinical strategy position Heat favorably in the marketplace.

Our Solution: ImPACT Therapy

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

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It is designed to fight cancer by activating the immune system against a wide variety of cancer antigens (both known and unknown).

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It is intended to continually secrete a wide variety of cancer-associated antigens, thus initiating a broad and sustained pan-antigen cytotoxic T cell attack against the targeted cancer. We believe this broad-based attack increases the probability of destroying the targeted cancer.

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It is designed to stimulate a natural immune response against specific cancer cells. We believe this may limit serious adverse events related to treatment.

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We believe that the novel mechanism of action, good tolerability and favorable safety profile will enable our *ImPACT*™ product candidates to have potential benefits across multiple disease stages and tumor types and in combination with other therapies. We believe our *ImPACT*™ technology can be targeted to additional specific tumor types by modifying cells from the cancer type of interest.

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Our *ImPACT*™ Therapy represents a first-in-class agent that functions as both an immune activator and an antigen-delivery vehicle. *ImPACT* is the only adjuvant technology platform currently known to us in clinical development that is specific to CD8+ cytotoxic T cell immune response, which is especially important for developing therapeutics in oncology as well as a number of other infectious disease indications.

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Our *ImPACT*™ Therapy is an off-the-shelf therapy and offers substantial manufacturing and costs advantages compared to autologous or "personalized" immunotherapies.

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We believe many patients who are too ill to tolerate chemotherapy due to the associated toxicities may be able to benefit from our *ImPACT* product candidates.

ImPACT TECHNOLOGY PLATFORM

ImPACT Background

Our *ImPACT* technology represents an 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. 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.

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HSP s have several functions including:

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Protecting tissues from pathogens by activating the immune system.

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Acting as a chaperone to:

o

Facilitate proper protein folding within the endoplasmic reticulum.

o

Enable proper function of toll-like receptors and the innate immune system.

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Carry damaged proteins to intracellular garbage disposals to be degraded into peptides (short chains of amino acids – that are protein fragments).

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Loading peptides onto another class of proteins known as MHC I molecules. MHC I molecules move to the cellular surface where they are monitored by the immune system.

HSP gp96 is one of the most abundantly expressed proteins in the human body and is expressed by all cells. It is normally retained within cells in a compartment called the endoplasmic reticulum (ER), where it facilitates the folding of newly synthesized proteins so that they may perform their various tasks properly. Gp96 is particularly important in the process of detecting antigens as it is present in all cell types and, it is able to recognize all antigens. It also induces the immune system to activate CD8+ (killer) T cells which then seek out and destroy the cells that are marked by

antigens. Gp96 is normally only contained inside the ER of cells, however when a cell dies an abnormal death through necrosis it breaks open and releases gp96 into the surrounding tissue microenvironment. *ImPACT* works by modifying the chemical structure of gp96 so that a cell can continuously 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, MD, Ph.D., the 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:

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

Published studies in mice showed that killer T cell activation was approximately 10 million times greater with *ImPACT*™ secreted gp96-Ig than with a corresponding gp96 protein injection. The modified cell secretes gp96 in a sustained release for several days after injection. This creates a sustained immune response. These data suggest that gp96-chaperoned peptides may represent the most efficient, robust pathway for presenting a cell s antigens to the immune system and activating killer T cell.

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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 native tumor-cell line, we believe that *ImPACT s* technology can develop a therapy that shares many common features with patients tumors of the same origin. We believe this blanket approach will provide each patient with a higher likelihood of a positive response to the therapy.

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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.

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May cause few side effects

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

The distinguishing characteristics of *ImPACT* are:

(i)

While most other immunotherapy approaches target only a single antigen, **Heat s patented approach uses modified heat shock proteins to stimulate an immune response against multiple antigens contained within cancer cells**

(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 native tumor-cell line that we believe expresses a wide array of those antigens most commonly expresses in a particular type of cancer. We believe this pan-antigen approach provides each patient with a higher likelihood of a response to the therapy.

(ii)

Heat s product candidates are made from off-the-shelf (allogeneic) cells and may therefore be **less expensive to manufacture than patient-specific (autologous) vaccines**. Heat s vaccines are mass-produced from a single source while other immunotherapy approaches require physicians to extract a patient s blood and/or cells, send them to a facility where a personalized vaccine is created, and then have shipped back to the physician for injection into the patient.

(iii)

While competing companies are developing therapies that are both off-the-shelf and which target multiple antigens, **Heat s *ImPACT* technology is the only off-the-shelf (allogeneic) vaccine known to us that directly induces cross-presentation to the CD8+ (killer) T cells, which are the cytotoxic arm of the immune system.** Stimulating these CD8 (killer) T cells through cross-presentation has recently been shown to be critical to the induction of effective anti-tumor immunity. We believe our product candidates are able to leverage gp96 to serve as their own powerful immune stimulant (adjuvant) while other companies technologies rely on the use of a secondary adjuvant like GMCSF or Alum.

Our Product Candidates and Clinical Development Programs

We have initiated development programs to target our *ImPACT* technology platform against a range of diseases, including non-small cell lung cancer and bladder cancer. We have begun dosing patients with NSCLC in a Phase 2 protocol with our first therapeutic vaccine, HS-110, in the third quarter of 2014. We have completed the Phase 1 portion and begun dosing patients in the Phase 2 portion of a Phase 1/2 clinical trial for bladder cancer in the fourth quarter of 2014. The inventor of Heat s technology platform and the Chairman of our Scientific Advisory Board has also completed a study in primates for the development of a therapeutic and prophylactic vaccine for the treatment and prevention of HIV. This study 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 in the discretion of the inventor. We have no funding obligation for such trials and the primary inventor is responsible for future development and research; nonetheless any research conducted by the primary inventor contributes to our body of research and we may choose to progress any such research to further clinical trials and incorporate such research into our future development plans.

Summary of HS-110 Clinical Trial

Phase 1 HS-110 Clinical Trial

Background

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

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

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

HS-110 provides evidence of a CD8-CTL IFN- 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-). These patients also exhibited an estimated median survival of 16.5 months (95% CI:7.1-20.0). In contrast, 4 patients were immune non-responders and survived 2.1, 2.3, 6.7, and 6.7 months, or a median survival of 4.5 months, which is consistent with the expected survival times in this patient population. The protocol required that we look for such responses, but, as is typical in immunotherapy, no partial or complete tumor responses were observed. The median one-year overall survival rate of patients in the study was 44%

(95% CI:21.6-65.1). For comparative purposes, while there was a wide range of survival times, the one-year overall survival rate in a published one-year, 43-patient, advanced lung cancer population was 5.5%. One of the late-stage lung cancer patients 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 pre-clinical published studies on *ImPACT* therapy.

HS-110 Safety

We believe HS-110 showed no overt toxicity. There were no serious adverse events (SAEs) that were considered by the trial investigator to be treatment-related. Most of the adverse events (AEs) were reported as mild or moderate (grade 1 or 2) with the most frequent being skin induration and rash that were transitory and usually resolved in 1 to 2 weeks. 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. In lieu of a dose escalation design, the design of the Phase I trial involved increasing the frequency of vaccination, while still retaining the total dose of vaccine cells administered. A more frequent vaccination schedule caused increased tumor rejection in preclinical models.

Adverse Events by Body System

	Number of Events	Severity
Body System	**(N=219)**	**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

	Number of Events

Injection Site Reaction (ISR)	**(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-) following vaccination.

CD8 IFN- 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- response. 20,000 purified patient CD8 T cells were stimulated with vaccine cells for 40h in ELI-spot plates and the frequency of IFN- secreting cells determined. + indicates first increase. Solid indicate immune response (IR+), dashed lines no response (IR −).

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

Clinical Response

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

The typical median survival period for late-stage lung cancer is 4.5 months for patients who are not receiving any treatment. Two of the fifteen patients who completed the first course of therapy were followed for over 3 years and 4 years, respectively. 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. While these results may be encouraging, apparent differences in outcome between population-based survival estimates and treatment groups from a clinical study can arise from differences other than drug treatment. The reliability of such comparisons must also be considered in light of the unblinded nature of the study data at the time that the comparator was chosen. Moreover, the wide range of values in the 95% confidence intervals in our study suggests that the actual median survival times could lie anywhere in the reported intervals.

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

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

***ImPACT* INDICATIONS**

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 is expected to account for 26% of all female cancer deaths and 28% of all male cancer deaths. An expected 221,200 people will be diagnosed with lung cancer in the United States in 2015. Of these lung cancers, roughly 85% are 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 2 Clinical Development

Our ongoing 123 patient randomized controlled Phase 2 study has been designed to investigate the combination of HS-110 with low dose cyclophosphamide versus chemotherapy alone in third-line and fourth-line NSCLC patients. The trial is 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. Patients randomized to the comparator arm are treated with one chemotherapy regimen until progression. Blood samples are 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 is overall survival; secondary endpoints follow objective responses and immune response. The trial will enroll 123 patients at approximately 20-30 investigative centers in the US and Australia over 2 years. Dosing began in the third quarter of 2014 and we expect to complete enrollment in the fourth quarter of 2015.

An additional multi-cohort trial (the DURGA trial) evaluating other combinations with HS-110 is expected to be launched in 1H 2015. Each arm will consist of 9 patients and will focus on identifying new combinations to advance into randomized Phase 2 trials. As preclinical data supports additional combination strategies, new arms will be added to the protocol. We expect preliminary data from the first cohort to be available by the end of 2015.

Bladder Cancer

Disease

In the United States, bladder cancer is the fourth most common type of cancer in men and the eleventh most common cancer in women. According to the National Cancer Institute, 1 in 42 men and women will be diagnosed with bladder cancer during their lifetimes, meaning more than half a million people are living with bladder cancer in the US. In 2015, an estimated 74,000 cases of bladder cancer will be diagnosed in the United States, and an estimated 16,000 deaths will occur. Available treatments are currently not effective, thus this remains an area of high unmet need.

Phase 2 Clinical Development

We are currently enrolling in a 100 patient randomized controlled 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. 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. We anticipate including approximately 10-15 clinical sites in the US with an enrollment period of 18-24 months.

The Phase 1 portion enrolled one cohort of 10 patients at low dose. Patients received weekly intradermal injections of HS-410 for 12 weeks followed by 3 monthly injections, and immune response will be evaluated at baseline, week 7, week 14 and week 29. The first 3 patients were enrolled at >2 week intervals to allow opportunity to assess safety and tolerability of HS-410. In the Phase 2 portion, 75 patients will be enrolled in 1:1:1 fashion to low-dose HS-410, high-dose HS-410, or placebo. The primary endpoint will examine disease-free survival bladder cancer. Other endpoints will include recurrence rate, progression rate and immune response. Dosing in the randomized, blinded Phase 2 portion began in the fourth quarter of 2014 and at the time of this report, the trial is approximately 10% enrolled.

On January 26, 2015, we announced positive data from two patients in the Phase 1 portion of our Phase 1/2 clinical trial of HS-410 in NMIBC. More specifically, analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG (*bacillus Calmette-Guerin*) followed by six weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When the patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. We also reported that with respect to a second patient, a non-specific immune infiltrate was noted on week seven to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. The second patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate. We are still evaluating many patients from our Phase 1 clinical trial of HS-410 in NMIBC and continuing our ongoing Phase 2 clinical study.

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.

Other Cancers

Our *ImPACT* -technology is a broad based approach and can be used to combat a variety of cancers. We continue to evaluate other indications for our *ImPACT* therapeutic vaccines and have developed cell lines for ovarian cancer, triple negative breast cancer and pediatric rhabdomyosarcoma. 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 19, 2011, with the vendor (the Manufacturing Agreement). The Manufacturing Agreement provides that the vendor will manufacture products based on our *ImPACT* technology intended for use in pharmaceutical or medicinal end products, including, without limitation, products in a final packaged form and labeled for use in clinical trials or for commercial sale to end users in accordance with the terms and conditions of individual statements of work. The Manufacturing Agreement requires that we purchase 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 used in the inventor s Phase 1, and in our Phase 2 clinical trial and HS-410 used in our Phase 1/2 clinical trial was and is currently manufactured under current good manufacturing practices, or cGMP. The vaccine is grown in large quantities, dispensed into individual doses, frozen in liquid nitrogen, 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 continue secreting gp96-Ig for a period of several days. These 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 Phase 2 study has already been produced, and preparations are underway to produce quantities required for trial completion and subsequent clinical trials. Sufficient material to complete the Phase 1 portion and part of the Phase 2 portion of the HS-410 Phase1/ 2 study has already been produced, and preparations are underway to produce quantities required for

trial completion and subsequent clinical trials.

Competition

The pharmaceutical industry and biologics industry are each highly competitive and characterized by a number of established, large companies, 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 s 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, biologics and small molecule drugs. Not only do we compete with companies engaged in various cancer treatments including radiology and chemotherapy but we also compete with various companies that have developed or are trying to develop immunology vaccines for the treatment of cancer. Certain of our competitors have substantially greater capital resources, large customer bases, broader product lines, sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than we do and have more established reputations as well as global distribution channels. Our most significant competitors, among others, are fully integrated pharmaceutical companies such as Eli Lilly, Bristol-Myers Squibb, Merck and Co , Novartis, AstraZeneca/MedImmune, Johnson & Johnson, Pfizer, MerckGaA and Sanofi-Aventis, and more established biotechnology companies such as Roche/Genentech, Amgen, Celgene, and competing cancer immunotherapy companies such as Kite, Juno, Transgene, Dendreon, New Link Genetics, Agenus, NovaRx, Aduro Biotech, Immunocellular, Immunovaccine, Oncothyreon, Oxford Biomedica, Bavarian Nordic, Celldex 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:

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develop and market products that are less expensive, more effective or safer than our future products;

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commercialize competing products before we can launch any products developed from our product candidates;

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operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;

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initiate or withstand substantial price competition more successfully than we can;

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have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;

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a more effectively negotiate third-party licenses and strategic relationships; and

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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, Roche/Genentech, Bristol Myers Squibb, Transgene, Oxford BioMedica; NewLink Genetics; Celldex/Pfizer; and Celgene.

The primary treatments for non-small cell lung cancer are surgery, radiation, chemotherapy and various combinations of each of these treatments. A large number of patients, particularly with advanced disease, are refractory to these treatments and are subsequently treated with a number of emerging biologic agents, including immunotherapy. Some examples of therapies commonly attempted with stage IIIB/IV NSCLC patients include: Alimta (pemetrexed), Avastin (bevacizumab), Tarceva (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.

As previously stated we compete with other forms of cancer treatment such as biologic therapies in addition to immunology therapies. There are several biologic therapies in clinical development for NSCLC that have been identified as potential competitors to HS-110. In particular, a cell-based vaccine therapy, Lucanix, is in development by NovaRx. Lucanix has recently completed Phase 3 clinical trials and failed to reach the primary endpoint, although these data have yet to be formally published.

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

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

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

Grant Funding

To date, in excess of $14,000,000 in grants, have been awarded to the primary inventor of the technology we license to fund development of *ImPACT* technology and clinical trials upon which our clinical programs are based. We have little control over the direction of the National Institutes of Health, (NIH) grant funds that have been received by the primary inventor of the technology we license and since payment is made to the inventors as opposed to us we do not recognize any revenue from such grant funds nor do they fund any expenses that we incur. Although earmarked for further development of the technology that we license, any funds awarded to the primary inventor are used in his discretion and we have little control over his use of the funds. Our strategy is to continue to apply for grants that will enable us to leverage our core technology platform. In the past we have applied for grant funding from the NIH, Department of Defense, Cancer Prevention Research Institute of Texas and other public and private foundations to be used for our research and development activities. Our primary inventor also applies for academic grants to enhance the core technology platform. Grant funds received by our primary inventor are not utilized by us. Rather, these funds support our primary inventor's academic interests and may benefit us to the extent that these grants enable him to enhance the technology platform or generate additional data to support our programs. Currently, our primary inventor's academic grants are supporting the HS-110 NSCLC combination study as well as the HIV study. All other clinical programs, including our Phase 2 NSCLC study and our Phase 1/2 bladder cancer study are supported by us.

Previous Grant awards for development of *ImPACT*

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

Intellectual Property

License Agreements and Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets and 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* therapy) and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. See Risk Factors - Risks Relating to Our Business We have limited protection of our intellectual property.

We will continue to depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our

interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

License Agreements

In July 2008, we entered into an exclusive license agreement with the University of Miami (the University) for intellectual and tangible property rights relating to 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:

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

As consideration for the rights granted in the license agreement, the licensee is obligated to pay the University upfront license fees, additional yearly and milestone payments and a royalty based on net sales of products covered by the patent-related rights set forth above. More specifically, the licensee is obligated to pay the University (i) all past and future patent costs associated with the licensed patent-related rights; (ii) a license issue fee of $150,000; (iii) annual payments of $10,000 in 2010, 2011 and 2012, and $20,000 each year thereafter; (iv) a milestone payment of $250,000 by the earlier of May 31, 2017 or approval of a BLA for the lung cancer vaccine or for a cancer vaccine other than lung cancer; and (v) royalties equal to a 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 of this license agreement.

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:

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

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U.S. patent application serial number 61/033,425 entitled Allogeneic Cancer Based Immunotherapy and filed on March 3, 2008 and PCT application number PCT/2009/001330 entitled Allogeneic Cancer Based Immunotherapy filed on March 3, 2009, all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the “Allogeneic Cancer –Based Immunotherapy Portfolio”).

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U.S. patent application serial number 61/033,425 entitled “Heat Shock Protein GP96 Vaccination and Methods of Using Same” filed on March 20, 2008 and PCT application number PCT/ 2009/001727 entitled Heat Shock Protein GP96 Vaccination and Methods of Using Same filed on March 19, 2009, all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the Heat Shock Protein GP96 Vaccination Portfolio”).

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U.S. patent application serial number 61/116.971 entitled “HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity” filed November 28, 2008 and PCT application number PCT/ 2009/065500” entitled “HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity filed on November 23, 2009 all U.S. patents and foreign patents and patent applications based on these U.S. applications as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the applications) of the foregoing, and any re-examinations or reissues of the foregoing (the HIV/SIV Vaccine Portfolio).

As consideration for the rights granted in these additional four license agreements, the licensee is obligated to pay the University certain upfront license fees, past and future patent costs and royalties based on net sales 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 Heat s Preferred Stock), the University agreed to postpone the payment due dates 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 use it best efforts to introduce, a licensed product in the commercial marketplace in the US, EU, or Japan by December 31, 2020; (ii) not otherwise exercise diligence to bring licensed products to market; or (iii) files, or has filed against it, a proceeding under the Bankruptcy Act, is adjudged insolvent, makes an assignment for the benefit of its creditors, or has an unreleased or unsatisfied writ of attachment or execution levied upon it.

In 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:

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U.S. Provisional Patent Application serial number 61/445,884 entitled “Combined Cell Based Gp96-IG-SIV/HIV; Recombinant Gp120 Protein Vaccination For Protection From SIV/HIV” and filed February 23, 2011 (the “884 application); PCT Application Serial No. PCT/US2012/26256 entitled Combined Cell Based Gp96-IG-SIV/HIV, Recombinant Gp120 Protein Vaccination For Protection From SIV/HIV and 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 Portfolio).

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 US, EU, or Japan by December 31, 2023; (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.

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 licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

Under the above-described license agreements with the University, we have obtained exclusive rights to six different patent families. These families comprise six PCT applications, ten issued patents, three allowed patent applications, and forty-eight pending patent applications which cover the United States, Europe and Japan as well as several other countries having commercially significant markets. 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 one issued US patent, one pending US application, two issued Australian patents, one allowed Canadian patent application, three granted European patents (collectively validated in 28 countries), one issued Japanese patent, and one allowed Japanese patent 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 US and some foreign countries), the term for patents in this family extends until 2019.

Heat Shock Protein gp96 Vaccination and Methods of Using Same

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

Allogenic Cancer Cell Based Immunotherapy

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

Cancer Treatment

This family of patent filings contains results from a Phase 1 clinical trial of human subjects with cancer. Within this family are one pending application each in the U.S., Canada, Australia, China, Europe, India, Israel, Japan, South Korea and Hong Kong. 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 issued Australian patent, one granted South African patent, two pending applications in the US, and one pending application Canada, China, Europe, India, the Philippines, Singapore, and Hong Kong. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2029.

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 pending application each in the U.S., Australia, Canada, China, Europe, India, Japan, the Philippines, South Africa, and South Korea. Not including any patent term adjustments or extensions, the term for patents in this family extends until 2032.

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

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U.S. patent application serial number 12/303,036 entitled “Perforin-2 Proteins” filed December 2, 2008 and U.S. patent application serial number 61/637.455 entitled “Perforin-2 Defense Against Invasive and Multi-drug Resistant Bacteria” filed on April 21, 2012; all U.S. patents and foreign patents and patent applications based on these U.S. applications; as well as all divisionals, continuations, and those claims in continuations-in-parts (to the extent they are sufficiently described in the aforementioned applications) of the foregoing, and any re-examinations or reissues of the foregoing.

In consideration for the option, we are obligated to pay the University an option fee of $2,000 and to reimburse the University $3,000 for past patent costs. The term of the option is twelve months and is extendible so long as we continue to pay ongoing patent expenses. We are currently in the process of negotiating the terms of an exclusive license for this portfolio.

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

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

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

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. 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 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.

In addition, we have entered into an agreement 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 we are in good standing and in compliance of our patent license agreements with the University relating to our *ImPACT* platform. There are no financial obligations on our part under the arrangement.

With enhanced internal research and development capabilities, we filed two provisional patent applications relating to compositions, methods and kits for the treatment of cancer in 2014.

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

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

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

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

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

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug or biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding $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 twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug or biologic products, or drug or biologic products that present difficult questions of safety or efficacy, to an advisory committee typically a panel that includes clinicians and other experts for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before

approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

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

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

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

Post-Approval Requirements

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

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

Orphan Drugs

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

Fast Track Designation and Accelerated Approval

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

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

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

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

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. No biosimilar or interchangeable products have been approved under the BPCIA to date. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation which are still being evaluated by the FDA.

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

Cell and Tissue Based Biologics

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

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

Disclosure of Clinical Trial Information

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

Non-U.S. Regulation

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

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level; 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 and medicinal chemistry, manufacturing, clinical

development and regulatory and quality assurance. We engage third parties on a limited basis to conduct portions of our preclinical research; however, we are not substantially dependent upon any third parties for our preclinical research nor do any of these third parties conduct a major portion of our preclinical research. Research and development expenses were $2,861,231 and $2,737,688 during the years ended December 31, 2014 and 2013, respectively.

Employees

As of March 27, 2015, we had a total of 15 employees, of which 14 are full-time employees and 1 is part-time. 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.

Legal Proceedings

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

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:

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continuing to undertake pre-clinical development and successfully enroll patients in clinical trials;

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participating in regulatory approval processes;

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formulating and manufacturing products; and

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conducting sales and marketing activities.

While various members of our management and staff have significant experience in conducting cancer trials, the Company, to date, has not successfully 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 pre-clinical 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.

We are substantially dependent on the success of our product candidates, HS-410 and HS-110 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 conducting Phase 2 clinical trials. 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.

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

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidates are subject to extensive regulation by the FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot commercialize our product candidates and will not have product revenues. For the foreseeable future, we will have to fund all of our operations from cash on hand, grants, our Square 1 Bank debt facility and, potentially, future offerings. We believe we have sufficient cash on hand to fund our current operating plans for the next 12 months. However, changes may occur that would consume our available capital, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, pre-clinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results.

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

For the years ended December 31, 2014 and December 31, 2013, we incurred a net loss of ($12,243,211) and ($6,609,864), respectively. We have an accumulated deficit of ($24,135,447) through December 31, 2014. 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 the market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

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

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seek regulatory approvals for product candidates;

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implement additional internal systems and infrastructure; and

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hire additional personnel.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses. 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.

If we do not meet the milestones for financing under our secured loans with Square 1 Bank, we may be forced to seek other sources of financing and if we default on our secured loan with Square 1 Bank we could be forced to suspend all operations.

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

Risks Relating to our Business

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

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

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

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

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

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

Our product candidates are in early stages of development.

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. For example, the only clinical study of HS-110 completed to date was by the inventor of the technology that we license and showed evidence of an immune response in late-stage NSCLC patients exposed to HS-110. However, our current Phase 2 clinical trial of HS-110 will use doses and dosing regimens which have previously been tested in only 0 to 3 subjects, and will be conducted in patients with less advanced disease who may have different responses. In addition, immune response is not an acceptable regulatory endpoint for approval, and no actual clinical or tumor responses were observed in that study. Moreover, the HS-110 Phase 1 trial involved a small sample size, was not blinded and was sponsored by an individual who has a significant financial interest in the success of the product candidate. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

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

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter

problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

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unforeseen safety issues;

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failure to determine appropriate dosing;

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greater than anticipated cost of our clinical trials;

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failure to demonstrate effectiveness during clinical trials;

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

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patient drop-out or discontinuation;

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inability to monitor patients adequately during or after treatment;

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

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

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

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

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

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

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed.

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

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

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

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

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cost-effectiveness of our products relative to competing products;

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convenience and ease of administration;

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potential advantages of alternative treatment methods;

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

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

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

Our development program 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.

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

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

We will rely 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. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational products for our Phase 2 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. For example, the manufacturer of the clinical trial material we intend to use for any future Phase 3 trials of HS-110 and of our commercial product, if approved, is a different manufacturer from the manufacturer of the inventor s completed Phase 1 trial of HS-110 and the early portion of our initial Phase 2 trial of HS-110. Accordingly, it may be necessary to evaluate the comparability of the HS-101 produced by the two different manufacturers during the third stage of our Phase 2 trial of HS-110.

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 of 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.

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

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

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

We currently have no sales, marketing or distribution capabilities. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator s strategic interest in the products under development and such collaborator s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will

depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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developing drugs, biologics and other therapies;

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undertaking pre-clinical testing and clinical trials;

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

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formulating and manufacturing drugs, biologics and other therapies; and

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

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

If we fail to successfully enforce our intellectual property rights, our competitive position could suffer, which could harm our operating results. Competitors may challenge the validity or scope of our patents or future patents we may obtain. In addition, our licensed patents may not provide us 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:

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

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abandon an infringing drug or therapy candidate;

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redesign our products or processes to avoid infringement;

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

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pay damages; or

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

We rely on licenses to use various technologies that are material to our business and if the agreements were to be terminated or if other rights 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, 2015, 2016, and 2017 our minimum royalty obligations under our licensing agreements, required to be paid with the passage of time, are $33,000, $33,000, and $283,000, respectively, and thereafter through December 31, 2022, $33,000 per year. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments. The license agreements also provide for certain developmental milestones. No assurance can be given that we will meet all of the required developmental milestones. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

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

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

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government and health administration authorities;

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private health maintenance organizations and health insurers; and

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other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and therapeutics. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payers satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such vaccines. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced.

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

Political, economic and regulatory influences are subjecting the health care industry to potential fundamental changes that could substantially affect our results of operations. U.S. and foreign governments, for example, continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, the government controls the pricing and profitability of prescription pharmaceuticals. In the 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 and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

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

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

Certain of our officers may have a conflict of interest.

Certain of our officers are currently working for the Company on a part-time basis. One such officer also works at other jobs and has discretion to decide what time he devotes to our activities, which may result in a lack of availability when needed due to responsibilities at other jobs.

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

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

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decreased demand for any approved product candidates;

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impairment of our business reputation;

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withdrawal of clinical trial participants;

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costs of related litigation;

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distraction of management’s attention;

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substantial monetary awards to patients or other claimants;

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loss of revenues; and

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the inability to successfully commercialize any approved drug candidates.

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

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

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

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

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difficulties in managing foreign operations;

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

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

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

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reduced protection for intellectual property rights;

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

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

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

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

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

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

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

Continuing concerns over 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. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve or continues to deteriorate, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

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

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

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

Risks Related to Our Common Stock

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

As of March 27, 2015, our officers and directors together beneficially own approximately 28.0% of our outstanding common stock on a fully diluted basis. Mr. Wolf, our Chairman of the Board and Chief Executive Officer, alone through his direct and indirect holdings beneficially owns approximately 16.4% of our outstanding common stock on a fully diluted basis. As a result, Mr. Wolf, alone will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in our control and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that we would not otherwise consider.

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

In 2009, we adopted a 2009 Stock Option and Restricted Stock Plan (the 2009 Plan). In 2014, we adopted a 2014 Stock Option and Restricted Stock Plan (the 2014 Plan). As of December 31, 2014, awards for 1,018,590 shares of common stock have been granted under the 2009 Plan and the 2014 Plan and there were 68,872 shares of common stock remaining available for grant under these plans. In addition, as of December 31, 2014, 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 which excludes 125,000 shares of common stock issuable at $12.50 per share upon exercise of warrants issued to the underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

Our Third Amended and Restated Certificate of Incorporation authorizes the issuance of 50,000,000 shares of our common stock and 8,212,500 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 Stock Option and Restricted Stock 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.

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

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. We have identified a material weakness in our internal controls with respect to our financial statement closing process of our consolidated financial statements for the year ended December 31, 2014. Our management discovered an effective oversight by those in charge of governance resulted in insufficient controls over timely financial statement preparation and review.

We have begun to take actions that we believe will substantially remediate the material weakness identified. In response to the identification of our material weakness, we: (i) have retained additional personnel including a controller, (ii) are in the process of establishing a review process for key aspects of our financial reporting process, and (iii) will seek to establish better operating controls and involve our board of directors in our internal controls process, which will involve establishing formal procedures to communicate deficiencies in internal controls on a timely basis, and encourage our board of directors to more actively participate in guiding management as it relates to internal control matters. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

Our management, including our Chief Executive Officer and Controller, 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.

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

As of March 27, 2015 we have 8,394,456 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 or 701 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.

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

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We believe that the proceeds we received from the sale of the shares in our initial public offering, our recent public offering and our private placement will provide us with sufficient working capital for at least the next twelve months. Thereafter, we expect to require additional funds in the future to conduct additional clinical trials. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing, including under our Controlled Equity Offering^{SM} sales agreement with Cantor Fitzgerald & Co. 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.

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

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

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 or the minimum stockholder s equity requirement, the NASDAQ Capital Market may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair our stockholders ability to sell or purchase our common stock when they wish to do so. In the event of a de-listing, we would take

actions to restore our compliance with the NASDAQ Capital Market s listing requirements, but we can provide no assurance that any action taken by us would result in our common stock becoming listed again, or that any such action would stabilize the market price or improve the liquidity of our common stock.

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 recent offering in ways with which stockholders may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from our recent public offering and additional future financings. The net proceeds from the recent public offering will 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 will have 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.

Resales of our common stock in the public market by our stockholders may cause the market price of our common stock to fall.

This issuance of shares of common stock in our recent public offering could result in resales of our common stock by our current stockholders concerned about the potential dilution of their holdings. In turn, these resales could have the effect of depressing the market price for our common stock.

Item 1B.

Unresolved Staff Comments

None.

Item 2.

Properties

Facilities

Our executive offices are located at 801 Capitola Drive, 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. Based on our current operational plans, we believe that such facilities are adequate for our operations for the near future. Prior to January 2014, we leased approximately 2,111 square feet of office space for monthly rent of $4,046.

Item 3.

Legal Proceedings

None.

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 last two calendar quarters during the year ended December 31, 2013 and the year ended December 31, 2014. 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 24, 2015 was $6.79 per share. As of March 27, 2015, 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, 2013		
Third quarter	$ 13.50	$ 9.01
Fourth quarter	$ 15.29	$ 7.01
YEAR ENDED DECEMBER 31, 2014		
First Quarter	$ 9.29	$ 6.09
Second Quarter	$ 6.80	$ 3.95
Third Quarter	$ 6.98	$ 3.81
Fourth Quarter	$ 7.31	$ 3.89

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, 2014.

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	581,842	$4.17	5,620
2014 Equity Incentive Plan	436,748	$6.21	63,252
Equity compensation plans not approved by security holders			
Total	1,018,590	$5.04	68,872

Subsequent to year-end, we issued Anil Goyal, Taylor Schreiber and Jeff Wolf options exercisable for 12,500, 10,000, and 12,500 vesting pro rata on a monthly basis over four (4) years as part of their 2014 bonus.

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.

Use Of Proceed From Registered Securities

In connection with our initial public offering in July 2013, 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 initial public offering, were $27 million and net proceeds received after underwriting commissions and offering expenses of $2.7 million were approximately $24.3 million. As of December 31, 2014, of the net proceeds raised in our initial public offering, approximately $14.5 million has been used for working capital purposes, including fixed asset purchases. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in the prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act other than as previously reported.

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 should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2014 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.

OVERVIEW

We are a biopharmaceutical company engaged in developing novel allogeneic, off-the-shelf cellular therapeutic vaccines to combat a wide range of cancers and infectious diseases. Our proprietary *ImPACT* - Immune Pan Antigen Cytotoxic Therapy has been designed to deliver live, genetically-modified, irradiated human cells which secrete a broad spectrum of disease-associated antigens together with a potent immune response stimulator called gp96. The secreted antigen-gp96 complexes educate and activate a patient s immune system to recognize and kill diseased cells. In cancer patients our *ImPACT* therapy is designed to generate anti-cancer immune responses by mobilizing and activating cytotoxic killer T cells that target multiple cancer antigens, thus harnessing a patient s own immune system to fight cancer.

Unlike autologous or personalized therapeutic vaccine approaches which require extraction and processing of cancer or blood from each individual patient, our *ImPACT* therapeutic vaccines use a do not require custom manufacturing. Rather our vaccines are made using existing human cell lines which can be mass-produced for immediate use in all patients with the same disease. As such, we believe our off-the-shelf, immunotherapy approach offers logistical, manufacturing and cost benefits compared to one-off autologous patient-specific approaches.

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 revenues and have financed our operations with net proceeds from the private placement of our preferred stock, our initial public offering in which we received gross proceeds of $27 million, and our recent public offering that was completed on March 16, 2015 (the Offering) of 1,886,000 shares of our common stock at a closing price of $6.50 per share for gross proceeds of $12.3 million and net proceeds to us of approximately $11.1 million. As of December 31, 2014, we had an accumulated deficit of ($24,135,447). We had net losses of ($12,243,211) and ($6,609,864) for the years ended December 31, 2014 and 2013, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and initiate 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. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We expect our existing cash will enable us to fund our current operating plan for at least 12 months. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so.

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 Company has elected to follow the extended transition period guidance provided for in Securities Act Section 7(a)(2)(B) for complying with new or revised accounting standards. The Company will disclose the date on

which adoption of such standards is required for non-emerging growth companies and the date on which the Company will adopt the recently issued accounting standards.

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:

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Stock-based compensation, and

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Research and development costs

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. Inherent in this model are assumptions related to expected stock-price volatility, option life, risk-free interest rate and dividend yield. As a newly public company 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 option 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 to research and development expense as incurred. Research and development costs consist primarily of license fees (including upfront payments), milestone payments, manufacturing costs, salaries, stock-based compensation and related personnel costs, fees paid to consultants and outside service providers for laboratory development, legal expenses resulting from intellectual property prosecution and other expenses relating to the design, development, testing and enhancement of our product candidates.

Recent Accounting Pronouncements

In July 2014, the FASB issued Accounting Standards Update (ASU) ASU No. 2014-10, *Development Stage Entities (*Topic 915*): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the removal of Topic 915, Development Stage Entities, from the FASB Accounting Standards Codification . A development stage entity is one that devotes substantially all of its efforts to establishing a new business and for which: (a) planned principal operations have not commenced; or (b) planned principal operations have commenced, but have produced no significant revenue. Current U.S. GAAP requires a development stage entity to present the same basic financial statements and apply the same recognition and measurement rules as established companies. In addition, U.S. GAAP requires a development stage entity to present inception-to-date information about income statement line items, cash

flows, and equity transactions. For public business entities, the presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted for financial statements that have not yet been issued or made available for issuance. The Company has elected to adopt the guidance as of June 30, 2014. The adoption did not impact the Company s financial position or results of operations.

In August 2014, FASB issued ASU 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 adoption of this guidance is not expected to have a material impact on the Company s consolidated financial statements.

In January 2015, the FASB issued ASU No. 2015-1, *Income Statement - Extraordinary and Unusual Items*. ASU 2015-01 will eliminate from U.S. GAAP the concept of extraordinary items and will no longer require an entity to separately classify, present, and disclose extraordinary events and transactions. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, and early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements or related footnote disclosures.

RESULTS OF OPERATIONS

Year Ended December 31, 2014 and 2013

Revenues

To date, our revenues have been entirely comprised of grant awards. There were no grant awards in 2014 and 2013. We will continue our efforts to secure future grant funding to subsidize ongoing research and developments costs.

Operating Expenses

Total operating expenses for the year ended December 31, 2014 (the 2014 Period) increased 86% to $12,186,927 compared to $6,564,641 for the year ended December 31, 2013 (the 2013 Period). Operating expenses are primarily comprised of research and development, clinical and regulatory and general and administrative expenses. For the 2014 Period, research and development expenses were $2,861,231, clinical and regulatory expenses were $5,348,091 and general and administrative expenses were $3,977,605 as compared to research and development expenses of $2,737,688, clinical and regulatory expenses of $1,397,157 and general and administrative expenses of $2,429,796 for the 2013 Period. For the year ended December 31, 2014, research and development expenses represented approximately 23% of operating expenses, clinical trials and regulatory represented approximately 44% of operating expenses, and general and administrative expenses represented approximately 33% of operating expenses. For the year ended December 31, 2013, research and development expenses represented approximately 42% of operating expenses, clinical trials and regulatory represented approximately 21% of operating expenses, and general and administrative expenses represented approximately 37% of operating expenses.

Research and development expense.

Research and development expense for the 2014 Period increased 5% to $2,861,231 compared to $2,737,688 for the 2013 Period. The $123,543 increase from the 2013 Period to the 2014 Period is primarily related to an increase of $286,111 in patent legal fees associated with licenses. Salaries and compensation related expense increased by $252,350 due to hiring over the course of the year. Administrative and allocated expense related to the expansion of the lab during 2014 increased by $206,417. Depreciation related to the lab facility was $59,719 compared to no expense in 2013. Travel expenses increased by $21,217 year over year. These increases were offset by $702,271 in pre-manufacturing costs as we began manufacturing clinical trial batches.

Clinical and regulatory expense.

Clinical and regulatory expense for the 2014 Period increased 283% to $5,348,091 compared to $1,397,157 for the 2013 Period. The $3,950,934 increase from the 2013 Period to the 2014 Period resulted from an increase of $1,955,309 in clinical trial execution, $1,183,959 in payments to investigators, specimen management and other clinical trial expenses, and $395,851 in drug development and manufacturing related to our clinical trials. Salaries and compensation related expenses for our clinical and research staff increased by $214,168 as we hired employees to support our clinical trials. Travel costs increased by $76,492 related to attendance at conferences. Administrative and allocated expense related to expanded headcount increased by $86,420. Additionally we established an Australian subsidiary and incurred goods and services tax of $38,735.

General and administrative expense.

General and administrative expense for the 2014 Period increased 64% to $3,977,605 compared to $2,429,796 for the 2013 Period. The $1,547,809 increase from the 2013 Period to the 2014 Period is primarily attributable to an increase in personnel costs of $786,595, including non-cash, stock-based compensation of $277,473. The increase in personnel costs is primarily related to an increase in pay to certain key employees. Additionally, public company expenses increased by $825,782 which include professional services such as accountants, attorneys and insurance due to the increased risk management requirements of a public company. Tax expense increased by $106,470 primarily as a result of increased franchise taxes due to the Company s becoming public. Additionally, travel costs increased by $226,695 from the 2013 Period to the 2014 Period as the Company executives attended more conferences. These increases are offset by a decrease of $315,656 in patent, license and trademark fees as much of that work was performed in 2013, and the Company merely maintained these assets in 2014. Additionally, facilities costs related to general and administrative expenses decreased by $82,077 in the 2014 Period as compared to the 2013 Period as these costs were allocated to other departments.

Interest income

Interest income increased to $40,570 for the 2014 Period from $10,068 for the 2013 Period. The $30,502 increase is due to the Company s increased cash balance that has been invested in various short-term financial instruments that generated interest income during 2014.

Interest expense

Interest expense decreased to $73,354 for the 2014 Period from $79,119 for the 2013 Period. In the 2013 Period, the Company had outstanding debt accruing interest for the majority of the year, while in the 2014 Period the Company only had outstanding debt from the end of August through the end of the year. The 2014 Period also includes the amortization of the debt discount and deferred financing fees.

Net loss attributable to common stockholders

The Company had a net loss attributable to common stockholders of $11.8 million, or ($1.83) per basic and diluted share for the year ended December 31, 2014 compared to a net loss of $9.1 million, or ($2.42) per basic and diluted share for the year ended December 31, 2013.

BALANCE SHEET AS OF DECEMBER 31, 2014 AND 2013

Investments, held to maturity (net)

Investments held to maturity (net) decreased to $10,698,982 for the 2014 Period from $17,297,165 for the 2013 Period. The decrease was primarily due to cash used in our operating activities.

Prepaid expenses.

Prepaid expenses were $863,227 as of December 31, 2014 compared to $1,066,638 as of December 31, 2013. The decrease of $203,411 was due primarily to a reduction in the amount paid in advance for clinical trial related costs.

Accounts Payable.

Accounts payable was $1,367,426 as of December 31, 2014 compared to $651,917 as of December 31, 2013. This increase of $715,509 was primarily related to an increase of volume as we increased activity related to clinical trials.

Accrued Expenses.

Accrued expenses was $805,968 as of December 31, 2014 compared to $503,050 as of December 31, 2013. The increase of $302,918 was primarily related to $126,988 increase for clinical trials, $124,775 increase for employee bonuses and related benefits due to expanded headcount, and $51,155 increase for accrued rent for office and laboratory facility.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

To date, we have not generated any net income. Since our inception in June, 2008, we have financed our operations principally through private placements (including our prior and recent loan from Square 1 Bank described below) and through our initial public offering, which we closed in July, 2013 and the closings of the partial exercises of the underwriter s over-allotment option, which we closed in August 2013 and September 2013. The total gross proceeds raised from the offering and over-allotment option were $27 million, before underwriting discounts and commissions and other offering expenses payable by the Company for net proceeds of approximately $24.3 million. In August 2014, the Company entered into a secured loan with Square 1 Bank (Loan). The Loan provides the Company with a term loan in the aggregate principal amount not to exceed $7,500,000 to be used to supplement working capital. The Loan is available to the Company in four tranches: $1,500,000 was released August 2014 (Tranche 1 Loan), $1,500,000 was released to the Company in December 2014, upon its enrollment of its first patient in its the Phase 2 clinical trial for HS-110 (Tranche 2 Loan), $2,250,000 will be available to the Company upon Square 1 Bank s receipt or before June 30, 2015 of evidence satisfactory to it of the initiation and continuation of the *ImPACT* cell line for a third indication (Tranche 3 Loan) and $2,250,000 will be available to the Company upon Square 1 Bank s receipt or before October 31, 2015 of evidence satisfactory to it of the full enrollment of our Phase 1/2 clinical trial for HS -410 (Tranche 4 Loan). We filed a shelf registration statement on Form S-3 where we may sell securities from time to time and in one or more offerings up to a total dollar amount of $50 million of securities. On October 23, 2014, the shelf registration statement was declared effective by the SEC. In October 2014, we entered into an ATM with Cantor Fitzgerald & Co. To date, we have not sold any shares of common stock under the ATM. In March 2015, we completed an offering (the Offering) of 1,640,000 shares of our common stock, and 246,000 additional shares of our common stock to cover over-allotments at an offering price of $6.50 per share. The net proceeds were approximately $11.1 million, after deducting underwriting discounts and commissions and other estimated offering expenses. We believe that the proceeds we received from our initial public offering, the Offering and the Loan will provide us with sufficient working capital to fund our current operating plans and capital expenditure requirements for at least 12 months. Thereafter, we expect to require additional funds in the future to conduct additional clinical trials. As of December 31, 2014, we had $14,514,415 in cash and cash equivalents, short term investments, and restricted cash.

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 increase in cash used in operating activities for the 2014 Period compared to the 2013 Period is due to an increase in clinical and regulatory expenses as we began clinical trials. Additionally, there was an increase in other operational costs primarily associated with increases in headcount as well as costs associated with being a public company.

Investing activities. Cash provided by investing activities in the 2014 Period included purchase of property and equipment as well as the proceeds from maturities and purchase of various short-term investments while in the 2013 Period the use of cash was primarily for the purchase of short-term investments.

Financing activities. Cash provided by financing activities during the 2014 Period was approximately $3.0 million related to the proceeds from the Loan and the exercise of stock options. During the 2013 Period, cash provided by financing activities was approximately $28.3 million related to the initial public offering, partial exercises of the over-allotment option as well as the exercise of options.

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 $24,135,447 through December 31, 2014. 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.

Our existing cash and short-term investments along with the term Loan will enable us to fund our current operating plan and capital expenditure requirements for at least the next 12 months. Thereafter, we intend to meet our financing needs through the issuance of equity or debt 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:

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the progress of our research activities;

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the number and scope of our research programs;

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the progress of our preclinical and clinical development activities;

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the progress of the development efforts of parties with whom we have entered into research and development agreements;

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our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;

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our ability to achieve our milestones under licensing arrangements;

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the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;

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the costs and timing of regulatory approvals; and

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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 (including through the ATM) 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. Other than the Loan which requires that we meet certain milestones in order to obtain funding, 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. 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 2015 through 2019 as of December 31, 2014.

	Year ended December 31,					
	2015	**2016**	**2017**	**2018**	**2019**	**Total**
License Agreements	$ 33,000	$ 33,000	$ 283,000	$ 33,000	$ 33,000	$ 415,000
Principal repayments on term loans	397,465	1,223,502	1,223,502	155,531		3,000,000
Interest payments on term loans	189,490	130,404	52,539	1,119		373,552
Lease Agreements	192,833	218,271	224,282	231,010	194,401	1,060,797
Total	$ 812,788	$ 1,605,177	$ 1,783,323	$ 194,400	$ 227,401	$ 4,849,349

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-26.

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 Chief Executive Officer and Controller, acting as our principal financial and accounting 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 Chief Executive Officer and Controller concluded that our disclosure controls and procedures are not effective at the reasonable assurance level due to the material weakness discussed in Risk Factors in Part I Item 1A of this Report. Risk Factors to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Controller, as appropriate, to allow timely decisions regarding required disclosure.

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 in Internal Control-Integrated Framework (1992). Based on the assessment, management concluded that, as of December 31, 2014, our internal controls over financial reporting were not effective based on those criteria. We have identified a material weakness in our internal controls with respect to our financial statement closing process of our consolidated financial statements for the year ended December 31, 2014. Our management discovered an effective oversight by those in charge of governance resulted in insufficient controls over timely financial statement preparation and review.

We have begun to take actions that we believe will substantially remediate the material weakness identified. In response to the identification of our material weakness, we: (i) have retained additional personnel including a controller, (ii) are in the process of establishing a review process for key aspects of our financial reporting process, and (iii) will seek to establish better operating controls and involve our board of directors in our internal controls process, which will involve establishing formal procedures to communicate deficiencies in internal controls on a timely basis, and encourage our board of directors to more actively participate in guiding management as it relates to internal control matters. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

Our management, including our Chief Executive Officer and Controller, acting as our principal financial and accounting 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

We have remediated the material weakness previously disclosed related to the design of monitoring controls used to assess the design and operating effectiveness of our internal control. The actions taken include, amongst others, (i) installing a new accounting system which allows us to implement appropriate procedures and processes necessary for adequate controls (ii) implementing month end and period end closing procedures and review processes for key aspects of our financial reporting process, (iii) designing, documenting and implementing policies and procedures; and (iv) instituting formal procedures for accounting for options.

No other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) occurred during our fiscal year ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our 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

On March 24, 2015, our board of directors determined to hold our 2015 Annual Meeting of Stockholders (the Annual Meeting) on July 23, 2015. The record date, time and location of the Annual Meeting will be as set forth in our proxy statement for the Annual Meeting. Because the date of the upcoming Annual Meeting is more than 30 days after the anniversary of the 2014 Annual Meeting, proposals to be included in our proxy statement for the Annual Meeting in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, must be received on or before April 20, 2015. Shareholders must deliver the proposals or nominations to our principal executive offices at the following address: Heat Biologics, Inc., Attn: Corporate Secretary, 801 Capitola Drive, Bay 12 Durham, NC 27713.

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	51	Chairman, Chief Executive Officer and Director	2008
Stephen J. DiPalma	56	Interim Chief Financial Officer	2015
Anil K. Goyal Ph.D.	51	Vice President of Business Development	2013
Melissa Price Ph.D.	41	Vice President of Clinical and Regulatory Affairs	2013
Taylor Schreiber	35	Vice President of Research and Development	2014
John Monahan, Ph.D.	68	Director	2009
Paul Belsky, MD	58	Director	2009
Michael Kharitonov, Ph.D.	51	Director	2009
Edward B. Smith	39	Director	2009
Louis C. Bock	50	Director	2013

All of the officers listed above are full-time employees of the Company other than Mr. DiPalma, our interim CFO who works on a part-time basis.

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

Mr. Wolf founded Heat Biologics in August, 2008. Prior to founding Heat, from June 1997 to March 2011, Mr. Wolf has served as managing director at Seed-One Ventures, LLC a 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.

Stephen J. DiPalma, ***Interim Chief Financial Officer***

Mr. DiPalma brings more than 25 years of experience in life sciences and healthcare, including founding two start-ups, working with venture-backed companies, subsidiaries of Fortune 100 firms and publicly traded companies, and his work as a Managing Director with Danforth Advisors, LLC clients. Previously, he served as the CFO of two public companies, and as CFO, Chief Operating Officer (COO), CEO or Director of eight privately held companies, in addition to his consulting clients. Mr. DiPalma participated in the successful reorganization of Cambridge Biotech from Chapter 11 bankruptcy protection into Aquila BioPharmaceuticals, led the effort to take RXi Pharmaceuticals public, and has extensive experience in international fund raising and corporate structuring. He was formerly Chairman of the Board of Cognoptix Inc., and is on the Board of Directors of Phytera, Inc. Mr. DiPalma received his M.B.A. from Babson College and his B.S. from the University of Massachusetts-Lowell.

Anil Goyal, Ph.D., ***Vice President of Business Development***

Dr Goyal joined Heat Biologics in December 2013 as Vice President of Business Development of the Company. Prior to joining Heat Biologics, Dr. Goyal served as President and Chief Executive Officer of Qualiber, Inc., a company which he co-founded, from April 2010 until December 2013 and Managing Director of OpenDoors Group, LLC, a company he founded, from August 2008 until December 2013. From January 2009 until January 2010, Dr. Goyal served as the Vice President of Business Development at Optherion, Inc. and from January 2003 until January 2008 he served as Vice President of Business Development of Serenex, Inc., an oncology company that was acquired by Pfizer. Prior thereto, he served in various key management and development positions at Millennium Pharmaceuticals, Genome Therapeutics Corporation and Merck & Co.

Melissa Price, Ph.D., ***Vice President of Clinical and Regulatory Affairs***

Dr. Price is responsible for coordinating the clinical development and operational efforts at Heat Biologics. Prior to joining Heat Biologics, Inc., Dr. Price served in various positions at INC Research including Vice President of Global FSP Solutions at INC Research from February 2012 until October 2013 and Executive Director, Strategic Alliance Management from January 2010 until February 2012. From June 2009 until January 2010, Dr. Price served as the Senior Director, Drug Development Partnerships at Novaquest, a Quintiles Company. Prior thereto, from 2006 until 2009 she served in various positions at INC Research. Dr. Price received her Ph.D. in Organic Chemistry from Yale University.

Taylor H. Schreiber Ph.D., ***Vice President of Research and Development***

Dr. Schreiber joined Heat Biologics in March 2014 as Vice President of Research and Development. Dr. Schreiber is the co-inventor of significant elements of the Company s *ImPACT* Technology platform and has been intimately involved in the progression of gp96 heat shock protein immunotherapy both as a Ph.D. researcher and as a post-doctoral fellow in the laboratory of Eckhard Podack, M.D., Ph.D., the inventor of Heat s *ImPACT* Technology platform. Dr. Schreiber joins the Company after completing the M.D. / Ph.D. program at the University of Miami Miller School of Medicine, which he attended from 2004 until February 2014. In 2010, Dr. Schreiber received his Ph.D. degree from the Sheila and David Fuente Program in Cancer Biology at the University of Miami Miller School of Medicine after completing the four year Ph.D. program. Following his degree, Dr. Schreiber completed a post-doctoral fellowship with Dr. Eckhard Podack, M.D., Ph.D. studying the immunobiology of TNFRSF25 from 2010-2012. Dr. Schreiber received the best overall research award at the National Student Research Forum in 2008 and was nominated as a Future Leader in Cancer Research by the American Association for Cancer Research in 2011. Dr. Schreiber is an emerging expert in the field of tumor immunology and TNFRSF25 biology.

Paul Belsky, M.D., *Director*

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

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

Louis C Bock, ***Director***

Louis C. Bock was a Managing Director of Scale Venture Partners, a venture capital firm, until June 2014. Mr. Bock joined Scale Venture Partners in September 1997 from Gilead Sciences, Inc., a biopharmaceutical company where he worked from September 1989 to September 1997. Prior to Gilead, he was a research associate at Genentech, Inc. from November 1987 to September 1989. He currently serves as a director of the following publicly traded companies: Orexigen Therapeutics, Inc., for which he also serves as a member of the Audit and Nominating and Governance committees, and Zogenix, Inc., for which he also serves as a member of the Audit, Compensation and Nominating and Governance committees. In addition, Mr. Bock serves on the board of directors of the following privately-held companies: Molecular Templates, CardioKinetix and Powervision and also serves on the board of directors of Arizona Technology Enterprises, LLC, a non-profit organization. Mr. Bock is responsible for Scale Venture Partners investment in Seattle Genetics, Inc. In the past five years, Mr. Bock has also served as a member of the boards of directors of the following publicly traded companies: diaDexus Inc and Horizon Pharma, Inc. Mr. Bock received his B.S. in Biology from California State University, Chico and an M.B.A. from California State University, San Francisco.

We selected Mr. Bock to serve on our Board because of his extensive clinical and leadership experience in the biotechnology and biopharmaceuticals industries, including experience in research, project management, business development and sales from his time at Gilead. His membership on other companies boards of directors, including positions on other audit and nominating/corporate governance committees provides him with extensive corporate governance knowledge and insight into issues faced by companies similar to ours.

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

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

with highest honors from University of California at Berkeley.

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

John Monahan, Ph.D., *Director*

Dr. Monahan is currently the Chief Technology Officer of Synthetic Biologics, Inc., a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. Dr. Monahan Co-Founded Avigen Inc. (NASDAQ:AVGN) in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products for the treatment of serious human diseases. Over a 12 year period as CEO of Avigen he raised over $235M in several private and public financings including its IPO. From 1989-1992, he was VP of R&D at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an Instructor at Baylor College of Medicine, Houston TX. He received his Ph.D. in Biochemistry in 1974 from McMaster University, Canada and his B.Sc. from University College Dublin, Ireland in 1969. Dr. Monahan is a board member of Tacere Therapeutics, CA. He is also a board member of a number of Irish biotech companies including Genable, Cellix, Luxcel, Identigen, Pharmatrin and GK Technologies.

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

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

Since January 2015, Mr. Smith has been the Chief Executive Officer of Z Trim Holdings Inc. (Z Trim) (OTC:ZTHO), a manufacturer of environmentally friendly agricultural functional ingredients and has been a board member of Z Trim since 2009. 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 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. He is currently a Director of Z Trim Holdings Inc. (OTC:ZTHO), a manufacturer of environmentally friendly agricultural functional ingredients.

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

Scientific Advisory Board and Clinical Advisory Board

In addition to our Board, we also have a scientific advisory board comprised of six individuals and a Clinical Advisory Board comprised of five individuals. The Scientific Advisory Board is responsible for providing scientific advice and for assessing the scientific progress of our research and development efforts. The clinical advisory board works with our clinical team 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 Advisory Board are compensated for their services. Drs. Allison, Stebbing and Nemunaitis are each entitled to receive $1,500 per board meeting in addition to a reimbursement for travel and related. In addition, Drs. Allison, Stebbing and Von Hoff each received options to purchase 15,000 shares of our common stock, which options vest over a four year period. Dr. Von Hoff is entitled to receive $4,000 per onsite advisory board meeting, $2,000 per telephonic meeting and an hourly rate of $500 per hour for consultative discussions with management. Dr. Podack is entitled to receive $7,500 per month not to exceed $25,000 per year for consulting services per University of Miami policy.

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

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

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

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

Gary Acton, M.D., *Clinical Advisor*

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., *Clinical Advisor*

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., *Clinical Advisor*

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.

John Nemunaitis, M.D., *Clinical Advisor*

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

Mark Schoenberg, M.D., *Clinical Advisor*

Dr. Schoenberg is the Bernard L. Schwartz Distinguished Professor of Urologic Oncology at The Johns Hopkins University. His clinical practice is centered on the care of patients with invasive bladder cancer. It has been announced that in April 2014, Dr. Schoenberg will assume the position of Chairman of the Department of Urology at Montefiore Medical Center and Albert Einstein College of Medicine of Yeshiva University, Bronx, New York. Dr. Schoenberg s research program has focused on the translational validation of urinary markers for the early detection of cancer, the development of regenerative medicine solutions to the challenges of lower urinary tract reconstruction, and minimally invasive therapies for urologic malignancies. He is the past chair of the Medical Advisory Board of the Bladder Cancer Advocacy Network, author of *The Guide to Living with Bladder Cancer*, co-editor of *The Textbook of Bladder Cancer*, a contributor to *Campbell s Urology*, and former seminars editor of the journal Urologic Oncology. Dr. Schoenberg has served as principal investigator and co-investigator on numerous clinical trials and from 2005-2009 served as the national principal investigator for the Early Detection Research Network (EDRN/NCI) validation trial of microsatellite analysis for bladder cancer detection. He received his M.D. from the University of Texas Health Science Center and completed residency at the Hospital of the University of Pennsylvania and a basic research and clinical urologic oncology fellowship at Johns Hopkins.

Committees of the Board of Directors

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 be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of The NASDAQ Stock Market, a director will only qualify as an independent director if, in the opinion of that company s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

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

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

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

Leadership Structure

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

2014 Director Compensation

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2014 regarding the compensation of our directors who at December 31, 2014 were not also named executive officers.

Name	Fees Earned or Paid in Cash	Option Awards(1)	Other Compensation	Total
Paul Belsky, MD	$ 35,000	$ 23,579	$	$ 58,579
Louis Bock	$ 32,000	$ 23,579	$	$ 55,579
Michael Kharitonov, Ph.D.	$ 37,000	$ 23,579	$	$ 60,579
John Monahan, Ph.D.	$ 37,000	$ 23,579	$	$ 60,579
Edward Smith	$ 35,000	$ 23,579	$	$ 58,579

(1)

In accordance with ASC 718 for the financial statement reporting purposes for stock options, the amounts in the Option Awards column reflect the fair value of 6,483 options granted on June 11, 2014 to each individual director 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 determined using the Black-Scholes-Merton model.

As of December 31, 2014 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
Paul Belsky, MD	33,441
Louis Bock	28,223
Michael Kharitonov, Ph.D.	41,050
John Monahan, Ph.D.	41,050
Edward Smith	33,441

Following our successful initial public offering and in light of the additional responsibilities being undertaken by our board members due to our transition to a public company, 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, commencing January 2014, directors who are not employees receive an annual cash fee of $25,000 as well as a cash fee of $5,000 for each committee on which they serve and the Chairman of the Audit and Compensation Committees receive an additional $2,000. Upon election to the Board, each non-employee director receives a grant of stock options exercisable for 21,740 shares of common stock vesting over four years having an exercise price equal to the fair market value of the common stock on the date of the grant. Each nonemployee director also receives an annual option grant on the date of the Annual Meeting of Stockholders having a value of $25,000 on such date, which for 2014 resulted in the issuance of options exercisable for 6,483 shares of common stock to each non-employee director.

Item 11.

Executive Compensation

Set forth below is the compensation paid or accrued to our executive officers during the years ended December 31, 2014 and December 31, 2013 that exceeded $100,000.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Options	Other (1)	Total
Jeffrey Wolf	2014	$381,893	$127,500 (2)	$346,600	$12,108	$868,101
Chairman and CEO	2013	$250,000	$125,000 (3)		$11,472	$386,472
Matt Czajkowski	2014	$162,500	$ 40,500 (2)	$ 73,300		$276,300
Former Chief Financial Officer(4)	2013	$ 65,645	$ 13,125 (3)	$277,970		$356,740
Anil Goyal	2014	$219,975	$ 49,500 (2)	$257,880		$527,355
Vice President of Business Development						
Melissa Price	2014	$210,000	$ 47,250 (2)	$ 43,870		$301,120
Vice President of Clinical and Regulatory Affairs	2013	$ 52,500	$ 10,000 (3)	$538,400		$600,900
Taylor Schreiber	2014	$174,411	$ 39,483 (2)	$191,300	$ 2,567	$407,761
Vice President of Research and Development						

(1)

Represents payment for health insurance.

(2)

This bonus was accrued in 2014 and paid in 2015.

(3)

This bonus was accrued in 2013 but paid in 2014.

(4)

Mr. Czajkowski resigned as our Chief Financial Officer effective March 15, 2015.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2014)

Name and Principal Position	Number of securities underlying unexercised options/ exercisable	Number of securities underlying unexercised options/ unexercisable	Option exercise price	Option expiration date
Jeffrey Wolf	10,965 (1)		$ 2.30	12/18/2019
Chairman and CEO	108,696 (1)		$ 0.71	4/7/2016
		100,000 (2)	$ 8.62	6/11/2024
Matt Czajkowski	20,244 (3)	18,120	$ 8.81	5/15/2023
Former Chief Financial Officer	2,083 (4)	7,917	$ 8.62	1/17/2024
Anil Goyal	10,000 (5)	30,000	$ 7.58	12/16/2023
Vice President of Business Development				
Melissa Price	15,625 (6)	34,375	$12.57	10/1/2023
Vice President of Clinical and Regulatory Affairs	416 (7)	9,584	$ 5.30	10/15/2024
Taylor Schreiber	10,415 (8)	39,585	$ 4.57	6/11/2024
Vice President of Research and 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 2017.

(3)

Issued on May 15, 2013, these options vest over a 36 month period and will be fully vested in May 2016. Mr. Czajkowski resigned as our Chief Financial Officer effective March 15, 2015. As of March 15, 2015, Mr. Czajkowski had 23,441 vested options which are exercisable up to the ten year anniversary of the date of grant and 12,786 unvested options which vested fully at the time of his resignation and are exercisable for 90 days after March 15,

2015.

(4)

Issued on January 17, 2014, these options vest over a 48 month period and will be fully vested in February 2018. Mr. Czajkowski resigned as our Chief Financial Officer effective March 15, 2015. As of March 15, 2015, Mr. Czajkowski had 2,708 vested options which are exercisable up to the ten year anniversary of the date of grant and 2,500 unvested options which vested fully at the time of his resignation and are exercisable for 90 days after March 15, 2015.

(5)

Issued on December 16, 2013, these shares vest over a 48 month period and will be fully vested in December 2017.

(6)

Issued on October 1, 2013, these shares vest over s 48 month period and will be fully vested in September 2017.

(7)

Issued on October 15, 2014, these shares vest over a 48 month period and will be fully vested in October 2018.

(8)

Issued on June 11, 2014, these shares vest over a 46 month period and will be fully vested in February 2018.

Employment Agreements

Following our successful initial public offering and in light of the additional responsibilities being undertaken by our management due to our transition to a public company, our Compensation Committee conducted an evaluation of the compensation of certain members of our management. In order to aid its decision-making, the Compensation Committee considered the compensation practices and the competitive market for executives at companies with which we compete for personnel and an independent compensation advisor was retained to conduct a study of our peer group compensation.

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 January 20, 2014. Mr. Wolf receives an annual base salary of $395,000 per year. He also may receive, at the sole discretion of the board, additional performance-based bonuses equal to up to 50% of this then outstanding base salary at the end of each year. Upon execution of the agreement, Mr. Wolf was issued options exercisable for 119,661 shares of our common stock. In addition, he is to receive certain options to purchase 2% of our fully diluted equity at an exercise price equal to the then current market price if our stock is traded on a nationally recognized exchange or NASDAQ and our market capitalization is at least $250 million for at least 5 days. In January 2014, in accordance with the terms of his amended employment agreement, Mr. Wolf was also granted options exercisable for 100,000 shares of common stock, vesting annually *pro rata* over a two-year period of time, subject to approval of the stockholders of the 2014 Equity Incentive Plan. The decision to amend Mr. Wolf s Employment Agreement to effect an upward adjustment in his compensation was substantially based on the Compensation Committee s review of competitive market information, including the study conducted by the compensation advisor. The competitive market information and peer group study results indicated that the overall compensation of our CEO was below market, in fact it was below the 25th percentile of the peer group, and that following the upward adjustment it remains below but closer to the 25th percentile of the peer group.

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

On May 15, 2013, we entered into an employment agreement with Matthew E. Czajkowski to act as our Chief Financial Officer, which was amended on January 20, 2014 and further amended on May 1, 2014. Mr. Czajkowski received an annual base salary of $165,000 per year for his provision of services to us for fifty-percent of his professional time. In addition, Mr. Czajkowski was eligible to receive, at the sole discretion of the board, additional performance-based bonuses equal to up to 50% of this then outstanding base salary at the end of each year. Upon execution of the agreement, Mr. Czajkowski was issued options exercisable for 38,364 shares of our common stock, which options are exercisable over a ten year period and vested monthly over three years at an exercise price of $8.81 per share. Mr. Czajkowski s employment contract provided for three month s severance pay upon termination not for cause (as defined in the agreement) and accelerated vesting of all options that would have vested within one year of such termination. The agreement also provided for payments in the event of death and disability. On March 9, 2015, we entered into a severance agreement with Mr. Czajkowski effective as of March 15, 2015. In accordance with the terms of the severance agreement, Mr. Czajkowski resigned as our Chief Financial Officer effective as of March 15, 2015, and we paid Mr. Czajkowski all accrued and unpaid base salary and an expense reimbursement in addition to $45,000. Mr. Czajkowski has the ability to exercise all stock options issued to him that vested prior to the date of resignation in accordance with the terms of his employment agreement at any time prior to the ten year anniversary of the date of grant and any unvested options at the time of resignation were immediately vested and are exercisable for 90 days after March 15, 2015. The severance agreement also contained additional provisions that are customary for agreements of this type, including confidentiality, non-competition and non-solicitation provisions.

On March 9, 2015, we entered into a consulting agreement (the Consulting Agreement) with Danforth Advisors, LLC (Danforth), for finance, accounting and administrative functions, including interim chief financial officer services provided by Mr. Stephen J. DiPalma. We will pay Danforth an agreed upon hourly rate for such services and will reimburse Danforth for expenses. The Consulting Agreement will continue until December 31, 2015 and may be extended by mutual agreement of the parties. The Consulting Agreement may be terminated by the Company with cause immediately and without cause, upon 30 days written notice.

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. Pursuant to the Goyal Employment Agreement, Dr. Goyal will be entitled to an annual base salary of $255,000 and will be eligible for discretionary performance bonus payments. Additionally, Dr. Goyal was granted an option to purchase 40,000 shares of our common stock with an exercise price equal to the Company s per share market price on the date of issue. These options vest *pro rata*, on a monthly basis, over forty-eight months. Dr. Goyal is also eligible to receive, on the one year anniversary of his employment, an option to purchase 12,500 shares of our common stock if certain milestones, which are yet to be agreed to, are met by such date. The Goyal Employment Agreement also includes confidentiality obligations and inventions assignments by Dr. Goyal. If Dr. Goyal s employment is terminated for any reason, he or his estate as the case may be, will be 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 Accrued Obligations); provided, however, that if his employment is terminated (1) by us without Just Cause (as defined in the Goyal Employment Agreement) or (2) by Dr. Goyal for Good Reason (as defined in the Goyal Employment Agreement) then in addition to paying the Accrued Obligations: (x) we shall continue to pay his then current base salary for a period of four months; (y) he shall receive a pro-rated amount of the annual bonus which he would have received during the year without the occurrence of such termination; and (z) he will have the right to exercise any vested options and any options that would have vested in the next four months until the earlier of the expiration of the severance or the expiration of the term of the option.

Effective October 1, 2013, we appointed Melissa Price, Ph.D. as our Vice President of Clinical and Regulatory Affairs, which was amended on January 20, 2014 and further amended on January 12, 2015. In connection with her appointment, Dr. Price entered into a four-year employment agreement with us (the Price Employment Agreement). Pursuant to the Price Employment Agreement, Dr. Price receives an annual base salary of $250,000 and will be eligible for discretionary performance bonus payments. Additionally, Dr. Price was granted an option to purchase 50,000 shares of our common stock with an exercise price equal to our per share market price on the date of issue. These options vest pro rata, on a monthly basis, over forty-eight months. Dr. Price was also eligible to receive, an option to purchase 10,000 shares of our common stock if certain agreed to milestones were attained and such options were issued in October 2014. The Price Employment Agreement also includes confidentiality obligations and inventions assignments by Dr. Price. If Dr. Price s employment is terminated for any reason, she or her estate as the case may be, will be entitled to receive the Accrued Obligations accrued by her to the extent not previously paid; provided, however, that if her employment is terminated (1) by us without Just Cause (as defined in the Price Employment Agreement) or by Dr. Price for Good Reason (as defined in the Price Employment Agreement) then in addition to paying the Accrued Obligations, (x) we shall continue to pay her then current base salary for a period of four months; (y) she shall receive a pro-rated amount of the annual bonus which she would have received during the year without the occurrence of such termination and (z) she will have the right to exercise any vested options and any options that would have vested in the next four months until the earlier of the expiration of the severance or the expiration of the term of the option.

Effective March 3, 2014, we appointed Taylor Schreiber, M.D., Ph.D., 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. Pursuant to the employment agreement, Dr. Schreiber receives an annual base salary of $250,000 and will be eligible for discretionary performance bonus payments. Additionally, on June 11,

2014, the date that the Company s stockholders approved our 2014 Stock Incentive Plan, we granted Dr. Schreiber an option to purchase 50,000 shares of our common stock with an exercise price equal to our per share market price on the date of issue ($4.57). These options will vest pro rata, on a monthly basis, over forty-eight months, with a certain percentage vesting immediately upon grant. Dr. Schreiber is also eligible to receive, on the one year anniversary of his employment, an option to purchase 10,000 shares of our common stock if certain milestones, which are yet to be agreed to, are met by such date. The employment agreement also includes confidentiality obligations and inventions assignments by Dr. Schreiber.

If Dr. Schreiber s employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the Accrued Obligations accrued by him to the extent not previously paid (the Accrued Obligations); provided, however, that if his employment is terminated (1) by the Company without Just Cause (as defined in the Employment Agreement) or by Dr. Schreiber for Good Reason (as defined in the Employment Agreement) then in addition to paying the Accrued Obligations, (x) the Company shall continue to pay his then current base salary for a period of four months; (y) he shall receive a pro-rated amount of the annual bonus which he would have received during the year without the occurrence of such termination and (z) he will have the right to exercise any vested options until the earlier of the expiration of the severance or the expiration of the term of the option.

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, 2014 other than an inadvertent late filing of a Form 4 by Melissa Price.

Code of Ethics

We have long maintained a Code of Conduct which is applicable to all of our directors, officers and employees. In addition, we have adopted a Code of Ethics for Financial Management which applies to our Chief Executive Officer, Chief Financial Officer, Treasurer and 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 27, 2015, 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 27, 2015 we had 8,394,456 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, Bay 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				
Paul Belsky, M.D. (Director)	47,190	26,506	73,696	*
Louis Bock (Director)		9,509	9,509	*
Stephen DiPalma				*
Anil Goyal, Ph.D.		14,635	14,635	*
Michael Kharitonov, Ph.D. (Director)(2)	49,960	34,341	84,301	1.0%
John Monahan, Ph.D. (Director)	1,211	34,115	35,326	*
Melissa Price, Ph.D. (3)	692	22,291	22,983	*
Taylor Schreiber, M.D., PhD (4)	39,132	15,622	54,754	*
Edward Smith (Director)(5)	697,303	26,506	723,809	8.6%
Jeffrey Wolf (Director, CEO, Treasurer & Secretary)(6)	1,233,726	170,963	1,404,689	16.4%
All Executive Officers & Directors, as a group (10 persons)	2,069, 214	383,185	2,452,399	28.0%
5% Stockholders(1)				
Aristar Capital Management, LLC(5)			697,303	8.3%
Orion Holdings V, LLC (6)			695,653	8.3%
Seed-One Holdings VI, LLC(6)			536,862	6.4%
FW Heat Biologics, LLC(7)			453,673	5.4%
Franklin Resources, Inc. (8)			763,300	9.1%

*less than 1%

(1)

Represents shares subject to options which are vested and exercisable within 60 days of March 30, 2015.

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(2)

Includes 49,960 shares of common stock held by Dr. Kharitonov. Dr. Kharitonov disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a 1(a)(2) promulgated under the Exchange Act) that he may have in the Sunrise Equity, LLC.

(3)

The 692 shares of common stock are held in custodial accounts in the names of Dr. Price s children, of which Dr. Price disclaims beneficial ownership except to the extent of any pecuniary interest (as defined in Rule 16a 1(a)(2) promulgated under the Exchange Act) that she may have.

(4)

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.

(5)

Information obtained from a Schedule 13D/A filed on January 8, 2015 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.

(6)

Includes 695,653 shares of common stock held by Orion Holdings V, LLC and 536,862 shares of common stock held by Seed-One Holdings VI, LLC, entities for which Mr. Wolf serves as the managing member. Mr. Wolf is deemed to beneficially own the shares held by such entities as in his role as the managing member he has the control over the voting and disposition of any shares held by these entities. Does not include 86,957 shares of common stock beneficially owned by Mr. Wolf s children s trust 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.

(7)

Information obtained from a Schedule 13G filed February 12, 2014 with the Securities and Exchange Commission filed on behalf of (i) FW Heat Investors, L.P. (the Fund), a Delaware limited partnership, (ii) FW Heat Genpar, LLC (the General Partner), a Delaware limited liability company, as the general partner to the Fund, and (iii) Jay H. Hebert, as the sole member of the General Partner (Hebert and, together with the Fund and the General Partner, the Reporting Persons). All 453,763 shares of Common Stock are held by the Fund. The mailing address of FW Heat Investors L.P is 201 Main Street, Fort Worth, Texas 76102.

(8)

Information obtained from a Schedule 13G filed with the Securities and Exchange Commission on February 9, 2015. Charles B. Johnson and Rupert H. Johnson, Jr. each own in excess of 10% of the outstanding common stock of Franklin Resources, Inc. (FRI) and are the principal stockholders of FRI. Franklin Advisor, Inc. a management subsidiary of FRI is also deemed to be a beneficial owner of the common stock owned by FRI. The address of Franklin Resources, Inc. is One Franklin Parkway, San Mateo, California 94403-1906.

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 following is a summary of transactions since January 1, 2014 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 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.

On January 12, 2015, we entered into an amendment to the Employment agreement with Anil K. Goyal, Ph.D., our Vice President of Business Development, dated December 16, 2013 to increase Dr. Goyal s annual base salary to $255,000.

On January 12, 2015, we entered into an amendment to the Employment agreement with Melissa Price, Ph.D., our Vice President of Clinical and Regulatory Affairs, dated October 1, 2013, as amended on January 20, 2014 to increase Dr. Price s annual base salary to $250,000.

On January 12, 2015, we entered into an amendment to the Employment agreement with Taylor Schreiber, M.D., Ph.D., our Vice President of Research and Development, dated March 3, 2014, to increase Dr. Schreiber s annual base salary to $250,000.

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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.

On March 9, 2015, we entered into a severance agreement with Mr. Czajkowski effective as of March 15, 2015. In accordance with the terms of the severance agreement, Mr. Czajkowski resigned as our Chief Financial Officer effective as of March 15, 2015, and we paid Mr. Czajkowski all accrued and unpaid base salary and an expense reimbursement in addition to $45,000. Mr. Czajkowski has the ability to exercise all stock options issued to him that vested prior to the date of resignation in accordance with the terms of his employment agreement at any time prior to the ten year anniversary of the date of grant and any unvested options at the time of resignation were immediately vested and are exercisable for 90 days after March 15, 2015. The severance agreement also contained additional provisions that are customary for agreements of this type, including confidentiality, non-competition and non-solicitation provisions.

On June 11, 2014 our five directors Dr, Belsky, Mr. Bock, Dr. Kharitove, Dr. Monahan, and Mr. Smith were granted 6,483 options each, with 100% vesting of the grant on the vesting commencement date of the following year, subject to remaining on the Board of Directors.

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, 2014 and 2013 by BDO USA, LLP.

	December 31, 2014	December 31, 2013
Audit Fees and Expenses (1)	$ 166,800	$ 254,622

(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, 2014 and 2013.

1. Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2014 and 2013
3. Consolidated Statements of Operations for the years ended December 31, 2014 and 2013
4. Consolidated Statements of changes in Stockholders Equity for the years ended December 31, 2014 and 2013
5. Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013
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 (1)
1.2	Controlled Equity Offering SM Sales Agreement dated October 10, 2014, between Heat Biologics, Inc. and Cantor Fitzgerald & Co. (2)
1.3	Underwriting Agreement, dated March 10, 2015, between Heat Biologics, Inc. and Aegis Capital Corp.(3)
3.1	Certificate of Incorporation filed on June 10, 2008(4)
3.2	Amended and Restated Bylaws, as currently in effect(4)
3.3	Amended and Restated Certificate of Incorporation filed on October 16, 2009(4)

3.4	Second Amended and Restated Certificate of Incorporation filed on December 16, 2011(4)
3.5	Third Amended and Restated Certificate of Incorporation, as currently in effect(4)
3.6	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on May 29, 2013(1)
4.1	2009 Stock Incentive Plan(4)##
4.2	First Amendment of the 2009 Stock Incentive Plan(4)##
4.3	Second Amendment of the 2009 Stock Incentive Plan(4)##
4.4	Third Amendment of the 2009 Stock Incentive Plan(4)##
4.5	Fourth Amendment of the 2009 Stock Incentive Plan(4)##
4.6	Warrant issued to Square 1 Bank(4)
4.7	Warrant issued to North Carolina Biotechnology Center(1)
4.8	Specimen Common Stock Certificate of Heat Biologics, Inc.(4)
4.9	Form of Stock Purchase Agreement by and among Heat Biologics, Inc. and the Series B investors (Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions have been filed with the Commission)(4)##
4.10	Form of Representative s Warrant (1)
4.11	Amendment to Stock Warrant with North Carolina Biotechnology Center(1)
4.12	2014 Stock Incentive Plan (5)##
4.13	Warrant issued to Square 1 Bank(6)
10.1	License Agreement (UMJ110) between the University of Miami and Heat Biologics, Inc. effective February 18, 2011 (4)**
10.2	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008(4)**
10.3	License Agreement (143) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 11, 2011(4)**

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(4)**
10.5	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 (4)**
10.6	Promissory Note with North Carolina Biotechnology Center dated December 14, 2011(4)
10.7	Loan Agreement with North Carolina Biotechnology Center dated December 14, 2011(4)
10.8	Common Stock Subscription Agreement between the University of Miami and Heat Biologics I, Inc. dated July 7, 2009(4)
10.9	Employment Agreement with Jeffrey Wolf dated December 18, 2009(4)##
10.10	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011(4)##
10.11	Lease with Europa Center dated as of November 18, 2011(4)
10.12	Non-Exclusive Evaluation and Biological Material License Agreement with American Type Culture Collection effective April 12, 2011(4) **
10.13	Manufacturing Services Agreement with Lonza Walkersville, Inc. dated as of October 20, 2011(2)
10.14	Assignment and Assumption Agreement dated June 26, 2009(4)
10.15	Termination Agreement UM97-114 dated June 26, 2009(4)
10.16	Loan and Security Agreement with Square 1 Bank dated August 7, 2012(2)
10.17	Employment Agreement with Jennifer Harris dated November 3, 2011 and amendment thereto dated May 1, 2013(1)##
10.18	Amendment to License Agreement (UM97-14) dated April 29, 2009(4)
10.19	First Amendment to Loan and Security Agreement with Square 1 Bank dated November 30, 2012(4)
10.20	Second Amendment to License Agreement (UMSS-114) dated August 11, 2009(4)
10.21	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011(4)
10.22	1st Lease Modification Agreement dated December 19, 2012(3)
10.23	Form of Co Sale and First Refusal Agreement by and among Heat Biologics, Inc. and the Series B investors(4)
10.24	Form of Voting Agreement by and among Heat Biologics, Inc. and the Series B investors(4)
10.25	Form of Investor s Rights Agreement by and among Heat Biologics, Inc. and the Series B investors(4)
10.26	Second Amendment to Loan and Security Agreement with Square 1 Bank dated January 14, 2013(4)
10.27	Third Amendment to Loan and Security Agreement with Square 1 Bank dated February 28, 2013(4)
10.28	Fourth Amendment to Loan and Security Agreement with Square 1 Bank dated March 19, 2013(4)
10.29	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013(4)
10.30	Fifth Amendment to the Loan and Security Agreement with Square 1 Bank dated April 18, 2013(4)
10.31	Employment Agreement with Matthew Czajkowski dated May 15, 2013(1)##
10.32	Form of Lock-up Agreement(1)
10.33	Form of Agreement with Series B Preferred Stockholders to amend Stock Purchase Agreement(1)
10.34	Employment Agreement, dated as of October 1, 2013, by and between Melissa Price and the Company(7)##
10.34	Employment Agreement, dated as of December 16, 2013, by and between Anil K. Goyal and the Company(7)##
10.35	Amendment to Employment Agreement, dated as of January20, 2014 between the Company and Jeffrey Wolf(8)##

10.36	Amendment to Employment Agreement, dated as of January20, 2014 between the Company and Melissa Price(8)##
10.37	Amendment to Employment Agreement, dated as of January20, 2014 between the Company and Matthew Czajkowski(8)##
10.38	Employment Agreement, dated as of March 3, 2014 between the Company and Taylor Schreiber (9)##
10.39	Lease Agreement dated January 24, 2014*
10.40	License Agreement (UMK-161) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective March 4, 2014(11) **
10.41	Amendment to Employment Agreement dated May 7, 2014,between the Company and Matthew Czajkowski(12)##
10.42	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.(13)
10.43	Amendment to Employment Agreement dated January 12, 2015 between the Company and Melissa Price(14)##
10.44	Amendment to Employment Agreement dated January 12, 2015 between the Company and Anil Goyal(14)##
10.45	Amendment to Employment Agreement dated January 12, 2015 between the Company and Taylor Schreiber(14)##
10.46	Severance Agreement, dated as of March 9, 2015 with Matthew Czajkowski (15)
10.47	First Amendment to Lease dated January 24, 2014*
10.48	Second Amendment to Lease dated January 24, 2014*

21.1	List of Subsidiaries*
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP) *
31.1	Certification of Jeffrey Wolf, Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a) *
31.2	Certification of Ann Rosar, Controller pursuant to Rule 13a-14(a)/15d-14(a) *
32.1	Certification of Jeffrey Wolf, Chief Executive Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *
32.2	Certification Ann Rosar, Controller 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 *

(1)

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).

(2)

Previously filed as an exhibit to the Registration Statement on Form S-3 filed with the Securities and Exchange Commission on October10, 2014 (File No. 333-199274)

(3)

Previously filed as an exhibit to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 13, 2014 (File No. 001-35994).

(4)

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).

(5)

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)

(6)

Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 15, 2014 (File No. 001-35994).

(7)

Previously filed as an exhibit to the Registration Statement on Form 8-K with the Securities and Exchange Commission on October 1, 2013.

(8)

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).

(9)

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)

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).

(11)

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).

(12)

Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2014 File No. 001-35994).

(13)

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).

(14)

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).

(15)

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).

*

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.

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 27, 2015

By: /s/ Ann A. Rosar
Ann A. Rosar
Controller
(Principal Financial and Principal Accounting Officer)
Date: March 27, 2015

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 27, 2015
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 27, 2015
/s/ Michael Kharitonov, Ph.D. Michael Kharitonov, Ph.D.	Director	March 27, 2015
/s/ Louis C. Bock Louis C. Bock	Director	March 27, 2015
/s/ Paul Belsky, MD Paul Belsky, MD	Director	March 27, 2015

/s/ Edward B. Smith Edward B. Smith	Director	March 27, 2015

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Heat Biologics, Inc.

Durham, North Carolina 27713

We have audited the accompanying consolidated balance sheets of Heat Biologics, Inc. as of December 31, 2014 and 2013 and the related consolidated statements of operations, stockholders equity, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Heat Biologics, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014**,** in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

BDO USA, LLP

Raleigh, North Carolina

March 27, 2015

HEAT BIOLOGICS, INC.

Consolidated Balance Sheets

	December 31, 2014	December 31, 2013
Current Assets		
Cash and cash equivalents	$ 3,714,304	$ 4,566,992
Investments, held to maturity (net)	10,698,982	17,297,165
Prepaid expenses and other current assets	863,227	1,066,638
Total Current Assets	15,276,513	22,930,795
Property and Equipment, net	445,534	53,753
Other Assets		
Restricted cash	101,129	1,252
Deposits	19,798	9,320
Related party receivable	48,642	24,946
Deferred financing costs, net	24,554	
Total Other Assets	194,123	35,518
Total Assets	$ 15,916,170	$ 23,020,066
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,367,426	$ 651,917
Accrued expenses and other payables	805,968	503,050
Accrued interest		25,364
Current portion of long term debt	397,465	
Total Current Liabilities	2,570,859	1,180,331
Long Term Liabilities		
Long term debt, net of discount and current portion	2,314,124	
Stock warrants liability		122,590
Total Liabilities	4,884,983	1,302,921
Commitments and Contingencies see Note 15		
Stockholders' Equity		
Common stock, $.0002 par value; 50,000,000 shares authorized, 6,492,622 and 6,375,426 issued and outstanding at December 31, 2014 and 2013, respectively	982	961
Additional paid in capital	35,894,823	34,337,591
Accumulated deficit	(24,135,447)	(12,346,630)

Total Stockholders' Equity - Less Non-Controlling Interest		11,760,358		21,991,922
Non-Controlling Interest		(729,171)		(274,777)
Total Stockholders' Equity		11,031,187		21,717,145
Total Liabilities and Stockholders' Equity	$	15,916,170	$	23,020,066

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.

Consolidated Statements of Operations

	Years ended, December 31,	
	2014	**2013**
Operating expenses:		
Research and development	$ 2,861,231	$ 2,737,688
Clinical and regulatory	5,348,091	1,397,157
General and administrative	3,977,605	2,429,796
Total operating expenses	12,186,927	6,564,641
Loss from operations	(12,186,927)	(6,564,641)
Interest income	40,570	10,068
Other (expense) income	(23,500)	23,828
Interest expense	(73,354)	(79,119)
Total non-operating income (expense)	(56,284)	(45,223)
Net loss	(12,243,211)	(6,609,864)
Net loss - non-controlling interest	(454,394)	(198,516)
Beneficial conversion charge		(2,300,000)
Preferred stock dividend		(361,668)
Net loss attributable to common stockholders	$ (11,788,817)	$ (9,073,016)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.83)	$ (2.42)
Weighted number of common shares used in net loss attributable to common stockholders - basic and diluted	6,454,866	3,747,357

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.

Consolidated Statements of Stockholders Equity

	Preferred Stock			Common			
	Series 1	Series A	Series B	Stock	Accumulated	Non-Controlling	Total Stockholders