HEAT BIOLOGICS, INC.
Form 10-K/A
October 10, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K/A

Amendment No. 1

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

For the fiscal year ended December 31, 2013

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)*
100 Europa Drive, Suite 420 **Chapel Hill, NC**	**27517**
(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 March 27, 2014, was approximately $29,384,995 based on $6.64, the price at which the registrant's common stock was last sold on that date. The registrant has provided this information as of March 27, 2014 because its common stock was not publicly traded as of the last business day of its most recently completed second fiscal quarter.

As of March 31, 2014, the issuer had 6,452,341 shares of common stock outstanding.

Documents incorporated by reference: None.

EXPLANATORY NOTE

Heat Biologics, Inc. (the Company) is filing this Amendment No. 1 on Form 10-K/A (this Amendment) to amend its Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission (the SEC) on March 31, 2014 (the Original 10-K).

This Amendment is being filed for the sole purpose of correcting a typographical error in the signature date on the Report of Independent Registered Public Accounting Firm in Part II, Item 8, which was dated March 31, 2013 instead of March 31, 2014. As required by the SEC, this Amendment includes new certifications pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act of 2002, filed as Exhibits 31.1, 31.2, 32.1 and 32.2, hereto.

Except as described above, the Company has not modified or updated the Original 10-K or the financial statements included therein or modified any disclosures contained in the Original 10-K. Accordingly, this Amendment, with the exception of the foregoing, does not reflect events occurring after the date of filing of the Original 10-K, or modify or update any disclosures affected by subsequent events. Consequently, all other information not affected by the correction described above is unchanged and reflects the disclosures and other information made at the date of the filing of the Original 10-K and should be read in conjunction with our filings with the SEC subsequent to the filing of the Original 10-K, including amendments to those filings, if any.

HEAT BIOLOGICS, INC.

FORM 10-K

TABLE OF CONTENTS

PART I

Forward-Looking Statements

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

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

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

HS-110

We have submitted a Phase 2 protocol to our open IND in non-small cell lung cancer (NSCLC) patients with our therapeutic vaccine candidate HS-110 (viagenpumatucel-L). HS-110 is a biologic product which consists of a lung cancer cell line that has been genetically modified using our *ImPACT* technology platform to secrete a wide range of lung cancer associated antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient s cancer. The Phase 2 trial will evaluate HS-110 in combination with low dose cyclophosphamide followed by sequential chemotherapy versus chemotherapy alone in third-line NSCLC patients. The trial will enroll 123 patients at approximately 20-30 investigative centers over 24 months. We anticipate recruitment to begin in the third quarter of 2014.

The inventor of the *ImPACT* technology that we license recently reported results from a Phase 1 open-label, single center clinical trial of HS-110 in patients with advanced NSCLC. We believe the results provide clinical evidence that HS-110 is capable of generating anti-cancer immune responses. Eighteen patients were vaccinated, and 15 of the 18 vaccinated patients completed the first course of three planned courses of therapy. Two patients completed all three planned courses of therapy (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 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), 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

We have initiated dosing in a Phase 1/2 bladder cancer trial with HS-410. HS-410 is a biologic product which consists of a bladder cancer cell line which has been genetically modified using our *ImPACT* technology platform to secrete a wide range of bladder cancer antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient s bladder cancer. To date, we have dosed 1 patient in our 93-patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 3-6 weekly intravesical bacillus Calmette-Guérin (BCG) immunotherapy installations. We anticipate including approximately 10-15 clinical sites with an enrollment period of 18-24 months. Patient recruitment began in December 2013.

Additional Indications

We continue to evaluate other indications for our *ImPACT* therapeutic vaccines and have developed a cell line for ovarian cancer and one for triple negative breast cancer. Our decision to further pursue either of these two 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. To date, in excess of $14,000,000 of funding has been awarded to the primary inventor of the technology we license by the National Institutes of Health (NIH) and through other research and clinical grants, which has been used to further develop our *ImPACT* technology platform that we license. We have little control over the direction of the NIH grant funds that have been received by the primary inventor of the technology we license and since payment is made to the inventors as opposed to us we do not recognize any revenue from such grant funds nor do they fund any expenses that we incur. Although earmarked for further development of the technology that we license, any funds awarded to the primary inventor are used in his discretion and we have little control over his use of the funds. The NIH is also currently fully funding the primary inventor s study of an HS-HIV

product candidate in non-human primates with a therapeutic and prophylactic vaccine for the treatment and prevention of HIV utilizing the *ImPACT* approach.

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

Product Candidate	Indication	Phase of Development	Upcoming Milestone(s)
HS-110	Non-Small Cell Lung Cancer (NSCLC)	Open commercial IND	2014 - Initiate Phase 2
HS-410	Bladder Cancer Adjuvant	Enrolling patients	2015 - Report Phase 1 data on immune response and safety

ImPACT Therapy Novel Pan-Antigen Immune Activation

Our *ImPACT* therapy is a novel technology platform designed to educate and stimulate the immune system to combat specific disease targets, such as cancer cells. *ImPACT* utilizes live attenuated, human-derived, genetically-modified cells to generate an array of tumor associated antigens and secrete an essential immunostimulatory protein called gp96-Ig . The secreted proteins are designed to generate an immune response against cancer cells by mobilizing and activating a patient s own killer T cells to target a broad array of different tumor antigens with the goal of eliminating cancer cells. In contrast with other vaccine technologies that target only one antigen, *ImPACT s* pan-antigen approach which may enable the body to induce and maintain an immune response against a broad array of tumor-specific proteins, by potentially providing a more robust and sustained immune response and limiting cancer cells ability to evade the immune system. We believe the clinical and pre-clinical results suggest that *ImPACT* generates anti-tumor immune responses capable of targeting and destroying tumors. We believe our novel, off-the-shelf, live cell therapy has the potential to be used to not only combat a wide range of cancers, but also against various infectious diseases, such as hepatitis C, malaria and HIV, for which non-human primate studies, which we believe are encouraging, have been completed. We have leveraged our existing infrastructure by developing additional product candidates in areas where we can use our proprietary technology. Our success will depend on the clinical and regulatory success of our product candidates and our ability to retain, on commercially reasonable terms, financial and managerial resources, which are currently limited. To date, we have not received regulatory approval for any of our product candidates or derived any revenues from their sales. Moreover, there can be no assurance that we will ever receive regulatory approval for any of our product candidates or derive any revenues from their sales. We should have sufficient capital to operate the company for at least 12 months.

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 submitted our Phase 2 clinical trial protocol for HS-110, our lead drug candidate, against non-small cell lung cancer (NSCLC) to FDA and intend to initiate the trial in the third quarter of 2014. Our Phase 2 trial will expand upon the Phase 1 results obtained by the primary inventor as described below. In the fourth quarter of 2013, we initiated a Phase 1/2 clinical trial against 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.

Our History

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 100 Europa Drive, Suite 300, Chapel Hill, NC 27517. 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 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. (of which we own a 92.5% interest), Heat Biologics III, Inc., Heat Biologics IV, Inc. and Heat Biologics GmbH unless otherwise indicated. In June 2012, we divested our 92.5% interest in Heat Biologics II, Inc., which resulted in Heat Biologics II, Inc. being classified as discontinued operations in our consolidated financial statements for the years ended December 31, 2012. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. We assigned our proprietary rights related to the development and application of our *ImPACT* Therapy for the treatment of non-small lung cancer to Heat Biologics III, Inc. and our proprietary rights related to the development and application of our *ImPACT* Therapy to the treatment of bladder cancer to Heat Biologics IV, Inc.

Strategy

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

.

Develop and obtain regulatory approval for our ImPACT-based products. We plan to initiate a Phase 2 clinical trial in NSCLC in Q3-2014 and are currently conducting a Phase 1/2 clinical trial in bladder cancer, which we initiated in Q4-2013. 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.

.

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.

.

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

.

Further expand our broad patent portfolio. We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to do so. We have obtained exclusive rights to five different patent families directed to therapeutic compositions and methods related to our vaccine platform and preclinical development programs for cancer. These families comprise six PCT applications, ten issued patents, two allowed patent applications, and forty- eight pending patent applications. These patents and applications cover the United States, Europe, and Japan as well as several other countries having commercially significant markets.

.

Manage our business with efficiency and discipline. We believe we have efficiently utilized our capital and human resources to develop and acquire our product candidates and programs, and create a broad intellectual property portfolio. We operate cross-functionally and are led by an experienced management team with backgrounds in developing and commercializing product candidates. We use project management techniques to assist us in making disciplined strategic program decisions and to attempt to limit the risk profile of our product pipeline.

.

Obtain additional grant funding. To more fully develop our *ImPACT* technology platform and its application to a variety of human diseases, we plan to continue to seek and access external sources of grant funding on our own behalf and in conjunction with our academic and other partners to support the development of our pipeline programs. While we intend to work with our academic partners to secure additional grant funding, these partners have no obligation to work with us to secure such funding. We also intend to continue to evaluate opportunities and, as appropriate, acquire or license technologies that meet our business objectives.

.

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

Disease Targets and Markets

The Oncology Market

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

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

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

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

Limitations of Current Cancer Therapies

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

.

Toxicity. Chemotherapeutic agents are highly toxic to the human body and very often cause a variety of significant and debilitating side effects, including, but not limited to, nausea and vomiting, bleeding, anemia and mucositis. Some targeted therapeutics have fewer systemic toxicities, but still typically have off-target effects such as gastrointestinal inflammation, severe skin reactions and breathing difficulties. These side effects limit a patient's ability to tolerate treatment and as such can deprive the patient of the potential benefit of additional treatments or treatment combinations that might otherwise destroy or prevent the growth of cancer cells. Once they become aware of the limited efficacy, limited increased survival and potentially significant toxicity of existing treatment alternatives, many

patients diagnosed with terminal cancer choose to limit or forego therapy in order to avoid further compromising their quality of life. Patients with advanced stage cancer also often cannot tolerate cancer therapy, and certain therapies can hasten death as the patient's health further deteriorates from the therapy applied.

.

Mechanism of action. While many current therapeutic approaches can be effective against specific targeted cells, the efficacy of these therapies in treating cancer over the long term generally is limited by the abundance and diversity of the cancer and tumor cells, which are believed to enable the targeted cells to adapt and become resistant to the current therapeutic approach over time.

.

Short-term approach. Other than tumor removal in a surgical procedure, curing the cancer is often not the intent or a potential outcome of many current cancer therapies. Rather, increased survival time is the primary focus of many currently marketed and development-stage cancer therapeutics. In this regard, many cancer therapies show only a modest impact on the overall survival of the patients and only affect the length of time that passes after treatment begins and before the patient s disease worsens or the patient dies.

.

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

Immunotherapy Overview

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

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

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

Immunotherapy Approaches

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

Passive Immunotherapy: Passive immunotherapies generally consist of monoclonal antibodies directed at a single disease-specific enzyme or protein on the surface of the targeted cells with the goal of either killing the targeted cells or preventing them from dividing. Rather than stimulate or otherwise use the body s immune system to initiate the

attack on the disease, the attack is made by the therapy which is produced *ex vivo*, or outside of the body. These therapies also are not usually personalized for the patient.

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

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

.

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

.

Most active immunotherapies employ defined antigens that are not effective against multiple types of cancer.

.

Most immunotherapies produce toxic effects resulting in damage to healthy tissues if the target antigen is absorbed by normal cells in addition to the targeted cancer or virus-infected cells.

.

Many patients may not be able to mount effective immune responses with immunotherapy due to tumor or virus induced immunosuppression of accessory cells such as CD4+ helper T cells, which are necessary for the immunotherapies to be effective but may be functionally impaired by the patient's disease.

.

It can be difficult to commercialize immunotherapies based on cells derived from individual patients in a cost-effective manner as a result of the added complexity, limited patient material for production of multiple doses, and the need to store and ship the individual doses.

.

Immunotherapies that rely on defined, off-the-shelf antigens or a single targeted antigen may have limited effectiveness because even within the same type of cancer, the genetic makeup and distinct antigens of a tumor can vary significantly from patient to patient.

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

Although many of the immunotherapies currently in clinical development have shown promising results, we believe that specific proprietary elements of the ImPACT platform, especially the specific targeting of tumor antigens to patient CD8+ T cells, combined with an appropriate clinical strategy (focused on non-immunogenic tumors) position Heat favorably to competitive compounds.

Our Solution: ImPACT Therapy

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

.

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

.

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

.

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

.

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

.

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

.

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

ImPACT TECHNOLOGY PLATFORM

ImPACT Background

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

HSP s have several functions including:

.

Protecting tissues from pathogens by activating the immune system.

.

Acting as a chaperone to:

o

Facilitate proper protein folding within the endoplasmic reticulum.

o

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

o

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

.

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

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 our 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 proteins. Dr. Podack demonstrated in the laboratory that gp96-Ig vaccination effectively cross-presented tumor specific antigens to immune cells, led to expansion of Cytotoxic T Lymphocytes (CTL) and the subsequent rejection of injected tumor cells. Importantly, these studies demonstrated that the secreted protein gp96-Ig maintained the critical characteristics of the native gp96 protein required to generate anti-tumor immune responses. Thus, *in vitro* proof-of-principle was established that the innovation, gp96-Ig, not only retained the desired properties of the native gp96 protein, but enhanced those functions and led to tumor-killing immune responses.

Our ImPACT technology platform:

.

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

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

.

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

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

.

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

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

.

May cause few side effects

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

The distinguishing characteristics of *ImPACT* are:

(i)

While most other immunotherapy approaches target only a single antigen, **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 the widest array of antigens common to a particular type of cancer. We believe this pan-antigen approach provides each patient with a higher likelihood of a response to the therapy.

(ii)

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

(iii)

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

Our Product Candidates and Clinical Development Programs

We have initiated development programs to target our *ImPACT* technology platform against a range of diseases, including non-small cell lung cancer and bladder cancer. We have submitted a Phase 2 protocol to our open IND with our first therapeutic vaccine, HS-110, against NSCLC in March 2014, and we initiated a Phase 1/2 clinical trial for bladder cancer in Q4-2013. Our lead scientist has also completed a study in primates for the development of a therapeutic and prophylactic vaccine for the treatment and prevention of HIV. This study continues to be fully funded by the NIH. The HIV trials were initiated by the primary inventor and to date have been funded by grants awarded to the primary inventor, which can be used in the discretion of the inventor. We have no funding obligation for such trials and the primary inventor is responsible for future development and research; nonetheless any research conducted by the primary inventor contributes to our body of research and we may choose to progress any such research to further clinical trials and incorporate such research into our future development plans.

Summary of HS-110 Clinical Trial

Phase 1 HS-110 Clinical Trial

Background

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

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

ONCOLOGY INDICATIONS of *ImPACT*

Lung Cancer

Disease

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

Clinical Development

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

After completion of the 18 patient Phase 1 trial, in which 15 patients completed the first course of three planned course of therapy and were evaluated, we successfully opened a new IND to conduct additional trials with HS-110 in patients with NSCLC. Our Phase 2 study, which has been submitted to the FDA, has been designed to investigate the combination of HS-110 with low dose cyclophosphamide followed by sequential chemotherapy versus chemotherapy alone in third-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 three weeks during maintenance. Upon first progression, patients will be treated with a regimen from the list of allowable chemotherapies with continued administration of HS-110 for up to 2 years. Patients randomized to the comparator arm will be treated with one chemotherapy regimen until first progression and then switched to an alternate chemotherapy regimen until second progression. Blood samples will be taken to evaluate the immune response and their correlation to overall survival, and where considered appropriate by the investigator, patients will be 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 over 2 years. We anticipate recruitment to begin in Q3-2014.

In addition to our Phase 2 study, our chief scientist has received a grant award from the Marcus Foundation that fully funds a 36 patient Phase 1/2 investigator-sponsored Phase 1/2 study for use of HS-110 as a combination therapy with theophylline and oxygen. This study is anticipated to begin during Q2 2014 and is listed as identifier NCT01799161.

Bladder Cancer

Disease

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

Clinical Development

The Bladder Cancer Phase 1/2 Trial

We opened an IND in support of HS-410 for bladder cancer with no clinical hold. The first protocol submitted to the IND is a 93 patient, Phase 1/2 trial to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 3-6 weekly intravesical bacillus Calmette-Guérin (BCG) immunotherapy instillations. We anticipate including approximately 10-15 clinical sites with an enrollment period of 18-24 months.

The Phase 1 portion will enroll two cohorts of 9 patients each to either a high or low dose group. Patients will receive 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 in each dose group will be enrolled at 2 week intervals to allow opportunity to assess safety and tolerability of HS-410. At the completion of the Phase 1 portion of the study, the dose resulting in the optimal safety and immune response will be advanced to Phase 2. In the Phase 2 portion, 75 patients will be enrolled in 2:1 fashion to HS-410 or placebo. Primary endpoint will examine time to 1st recurrence of bladder cancer. Other endpoints will include recurrence rate, progression rate and immune response.

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 a cell line for ovarian cancer and one for triple negative breast cancer. 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.

Infectious Diseases

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

Manufacturing

We rely on third-party manufacturers to produce and store our product ca