UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from ____________ to ____________

Commission File Number: 001-35994

HEAT BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**26-2844103**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification Number)*
627 Davis Drive, Suite 400 **Morrisville, NC**	**27560**
(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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0002 par value per share	HTBX	The Nasdaq Capital Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every interactive data file required to be submitted 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 such files). Yes ☑ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standard provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $23,393,203 (based upon the closing sale price of the registrant's common stock reported on the Nasdaq Capital Market on that date). This calculation excludes shares held by the registrant's current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

As of March 23, 2020, the issuer had 79,384,021 shares of common stock outstanding.

Documents incorporated by reference: None.

HEAT BIOLOGICS, INC.

FORM 10-K

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PART I

Forward-Looking Statements

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

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

Item 1. *Business*

Overview

We are a biopharmaceutical company engaged in the development of immunotherapies, vaccines and diagnostics. Our gp96 platform is designed to activate the immune system. This platform has broad applications in cancer and infectious disease. Our T-cell Activation Platform (TCAP), leverages gp96's role as a natural molecular warning system to secrete cancer antigens. TCAP includes two variations for intradermal administration, Immune Pan-antigen Cytotoxic Therapy (*ImPACT*®) and Combination Pan-antigen Cytotoxic Therapy (*ComPACT*℠). HS-110 (viagenpumatucel-L) is our first allogeneic ("off-the-shelf") cell line biologic product candidate in a series of proprietary *ImPACT*® based immunotherapies designed to stimulate a patient's own T-cells to destroy cancer. HS-130 is an allogeneic cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD8+ T-cell response. We have initiated development of a new COVID-19 vaccine program that utilizes the gp96 platform to secrete SARS-CoV-2 antigens. In parallel, we are working with the University of Miami, to develop a COVID-19 point-of-care diagnostic test designed to utilize a simple pharyngeal throat swab to deliver on-the-spot results on a paper strip in under 30 minutes. Our subsidiary Pelican Therapeutics, Inc., is developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting TNFRSF25 for systemic administration. These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We have completed recruiting patients in our Phase 2 HS-110 non-small cell lung cancer (NSCLC) trial, have dosed our first patient in our first Phase 1 clinical trial of HS-130 and anticipate clearance by the U.S. Food & Drug Administration (FDA) of an IND for our PTX-35 program in the second quarter of 2020. We are also providing pre-clinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest. As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs.

About TCAP

In July 2019, we completed patient enrollment in our Phase 2 clinical trial for HS-110 in advanced NSCLC, that administered HS-110 in combination with either Bristol-Myers Squibb's anti-PD1 checkpoint inhibitor nivolumab (Opdivo®) or more recently, Merck & Co., Inc.'s (Merck's) anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®). We also announced interim results of this study in November 2019. Promising clinical activity was observed in our Phase 2 trial in NSCLC patients whose disease has progressed after prior treatment with a checkpoint inhibitor (CPI).

Our T-cell Activation Platform (TCAP), which includes a variation of two TCAPs, *ImPACT*® and *ComPACT*™, is designed to activate and expand tumor antigen specific "killer" T-cells to destroy a patient's cancer. By turning immunologically "COLD tumors HOT," we believe our platform will become an essential component of the immuno-oncology regimen to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

We believe this is a highly differentiated approach as our platform delivers a broad range of tumor antigens that are previously unrecognized by the patient's immune system. TCAP combines these tumor antigens with a powerful, naturally occurring immune adjuvant, gp96, to actively chaperone these antigens. Our TCAP product candidates are non-replicating, "off-the-shelf", allogenic cell-based therapies that are locally administered into the skin. The treatment primes local natural immune recognition to activate T-cells to seek and destroy the cancer cells throughout the body. These TCAP agents can be administered with a variety of immuno-modulators to enhance a patient's immune response through T-cell activation.

Unlike many other "patient specific" or autologous immunotherapy approaches, our drugs are fully allogenic, "off-the-shelf" products which means that we can administer them immediately without the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment based on these patient materials. Our TCAP product candidates are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. Because each patient receives the same treatment, we believe that our immunotherapy approach offers superior speed to initiation, logistical, manufacturing and importantly, cost benefits, compared to "personalized" precision medicine approaches.

About *ImPACT*®

Our *ImPACT*® platform is an allogenic cell-based, T-cell-stimulating platform that functions as an immune activator to stimulate and expand T-cells. The key component of this innovative immunotherapy platform is the dual functionality of the heat shock protein, gp96.

As a molecular chaperone, gp96 is typically found within the cell's endoplasmic reticulum and facilitates the folding of newly synthesized proteins for functionalized tasks. When a cell abnormally dies through necrosis or infection, gp96 is naturally released into the surrounding microenvironment. At this moment, gp96 becomes a Danger Associated Molecular Protein, or "DAMP", a molecular warning signal for localized innate activation of the immune system. In this context, gp96 serves as a potent adjuvant, or immune stimulator, via Toll-Like Receptor 4/2 (TLR4 and TLR2) signaling which serves to activate professional antigen presenting cells (APCs), such as dendritic cells that upregulate T-cell costimulatory ligands, major histocompatibility (MHC) molecules and immune activating cytokines. It is among the most powerful adjuvants found in the body and uniquely shows exclusive specificity to CD8+ "killer" T-cells through cross-presentation of the gp96-chaperoned tumor associated peptide antigens directly to MHC class I molecules for direct activation and expansion of CD8+ T-cells. Thus, gp96 plays a critical role in the mechanism of action for our T-cell activating platform immuno-therapies; mimicking necrotic cell death and activating a powerful, tumor antigen-specific T-cell immune response to attack the patient's cancer cells.

About *ComPACT*®

ComPACT™, our second TCAP, is a dual-acting immunotherapy designed to deliver antigen-driven T-cell activation and specific co-stimulation in a single product. *ComPACT*™ is designed to help unlock the body's natural defenses and builds upon *ImPACT*® by providing specific co-stimulation to enhance T-cell activation and expansion. This technology has the potential to simplify combination immunotherapy development for oncology patients, as it is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) as a single therapeutic, without the need for multiple, independent biologic products. The potential advantages of *ComPACT*™ include: (a) enhanced activation of antigen-specific CD8+ T-cells; (b) serving as a booster to expand the number of antigen-specific CD8+ and CD4+ T-cells compared to OX40L alone; (c) stimulation of T-cell memory function to remain effective in the body after treatment, even if the cancer comes back; (d) demonstration of less toxicity, as the source of cancer associated antigens and co-stimulator are supplied at the same time locally and the draining lymph nodes, which drive targeted, cancer specific immunity towards the tumor rather than throughout the body; and (e) a potential paradigm shift that is designed to simplify combination cancer immunotherapy versus systemic co-stimulation with conventional monoclonal antibodies (mAbs).

About COVID-19 Vaccine

Besides its utility in oncology, our gp96 platform also activates the human immune system to combat infectious diseases. Our collaborators have laid a good foundation on engineering different pathogenic antigens into our platform. Previous preclinical studies using gp96 platform includes SIV/HIV, malaria and Zika. We initiated a COVID-19 vaccine program in collaboration with the University of Miami in March 2020.

About COVID-19 Diagnostic Test

In March 2020, the Company initiated a new program, in collaboration with the University of Miami, to develop a point-of-care, rapid COVID-19 diagnostic test designed to utilize a simple pharyngeal throat swab to deliver on-the-spot results on a paper strip in under 30 minutes, and can be deployed in different settings without laboratory equipment. Unlike tests that detect antibodies (IgG and IgM method), which can take weeks to manifest, our test is being developed to utilize molecular recognition and amplification of the target virus. This point-of-care diagnostic test is being designed to address many of the challenges facing existing tests, including time to readout and cost.

About PTX-35

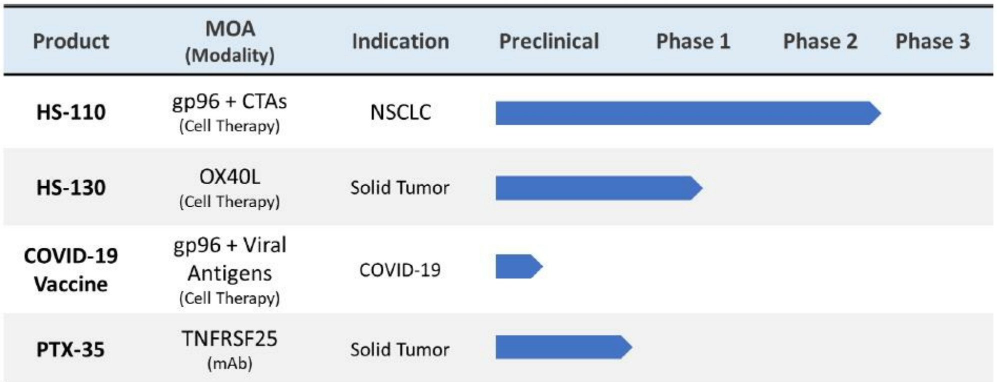
Pelican Therapeutics, Inc. (“Pelican”), our majority owned subsidiary, is a biotechnology company focused on the development of biologic based therapies designed to activate the immune system.

Pelican is currently developing an agonist mAb, PTX-35, against a T-cell costimulatory receptor, TNFRSF25. PTX-35 has completed IND-enabling activities in preparation for a first-in-human (FIH) trial for an oncology indication. PTX-35 is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. TNFRSF25 agonism has been shown to provide highly selective and potent stimulation of antigen experienced ‘memory’ CD8+ cytotoxic T-cells, which are the class of long-lived T-cells capable of eliminating tumor cells in patients. Due to the preferential specificity of PTX-35 to antigen experienced CD8+ T-cells, this agent represents a promising candidate as a T-cell co-stimulator in cancer patients.

When combined in preclinical studies with *ImPACT* ® and *ComPACT* ™ platform immunotherapies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target TNFRSF25 for various immunotherapy approaches, including PTX-45, a human TL1A-lg like fusion protein designed as a shorter half-life agonist of TNFRSF25.

Product Candidates in Development

The following table summarizes the product candidates for which we are engaged in development activities.



Clinical Pipeline

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

Using our licensed *ImPACT*® platform technology, we developed the product candidate, HS-110 (viagenpumatucel-L) as a potential treatment for patients with advanced non-small cell lung cancer. HS-110 is our first lead biologic product candidate designed to stimulate a patient's own T-cells to attack tumor cells. HS-110 is made of a lung adenocarcinoma cancer cell line that has been genetically modified to secrete a wide range of cancer-associated antigens bound to gp96 proteins, thereby activating a broad, T-cell medicated immune response against a patient's cancer.

We are currently conducting a Phase 2 trial of HS-110, in combination with either nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor or more recently, Merck's anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®), to treat patients with advanced NSCLC. The multicenter clinical trial evaluates the safety and efficacy of HS-110 in combination with nivolumab in a second line or greater setting, or with pembrolizumab in the front-line maintenance setting. Promising interim results suggest that HS-110 plays an integral role in tumor reduction and may enhance clinical benefit in patients receiving checkpoint inhibitors therapies. Primary and secondary trial endpoints include safety and tolerability, objective response rate, duration of response, and progression-free and overall survival. The trial has completed enrollment with a total of 122 patients.

HS-130

We have initiated clinical development of HS-130 for the treatment of advanced solid tumors. This product is designed to test our *ComPACT*™ technology approach. HS-130 intradermal delivers T-cell co-stimulatory fusion protein (OX40L). We have completed preclinical characterization and manufacturing activities for this product candidate.

Our first-in-human study is a dose-escalation study evaluating escalating doses of HS-130 in combination with HS-110 in up to 30 patients. The primary endpoints are to evaluate patient safety and to determine the optimal dose for a subsequent Phase 2 trial.

Preclinical Pipeline

COVID-19 Vaccine

Our wholly-owned subsidiary, Zolovax, Inc. ("Zolovax"), is focused on developing preventative medicines such as vaccines for infectious diseases based on our gp96 platform. Our collaborators have laid a good foundation on engineering different pathogenic antigens into our platform. Previous preclinical animal studies conducted includes simian immunodeficiency virus, malaria and Zika. We have initiated development of a COVID-19 vaccine program in collaboration with the University of Miami in March 2020. We utilize our proprietary gp96 platform to engineer multiple protein regions of the virus to activate the human immune system to combat COVID-19. Such design has the potential of generating long-term immune responses and may confer immunity to different coronaviruses.

PTX-35

Pelican Therapeutics, our subsidiary, is focused on the development of monoclonal antibody and fusion-protein based therapies designed to activate antigen experienced T-cell subsets of the immune system. Pelican's lead product PTX-35 is currently in preclinical studies. This is a humanized, affinity matured, monoclonal antibody that serves as a functional agonist of human tumor necrosis factor receptor superfamily member 25 (TNFRSF25), also known as death receptor 3 (DR3). This antibody stimulates antigen experienced 'memory' CD8+ cytotoxic T-cells with high specificity and potency. These cells are instrumental in destruction of tumor cells. Prior to our acquisition of 80% of Pelican in 2017, Pelican completed (1) humanization and affinity maturation of PTX-35; (2) PTX-35 epitope mapping or mapping of the binding site on the TNFRSF25 that is recognized by PTX-35; and (3) stability/development studies of PTX-35. We have begun manufacturing activities for this product candidate.

Preclinical studies with the murine precursor of PTX-35 shows advantages over competing T-cell co-stimulator programs based on the expansion of tumor antigens specific CD8+ T-cells. We plan to begin our first clinical study of PTX-35 by the third quarter of 2020.

PTX-45

PTX-45 (next generation improvements over PTX-35) is a human fusion protein that acts as an agonist of TNFRSF25 signaling with many of the advantages of PTX-35 described above with increased potency and a shorter *in vivo* half-life. We have continued preclinical candidate selection activities for PTX-45.

Additional Indications

We continue to evaluate additional indications for the *ImPACT*® and *ComPACT*℠ platform technologies, along with the PTX-35 and PTX-45 compounds. Specifically, using *ComPACT*℠, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy with similar cancer associated antigen overlap in multiple solid tumors (HS-130). Our decision to further pursue any product candidates, or any additional product candidates, will be based in part upon available funding and partnering opportunities.

The success of our *ImPACT*® and *ComPACT*℠ platform therapies will depend on the clinical and regulatory success of our product candidates and our ability to retain, on commercially reasonable terms, financial and managerial resources, which are currently limited. To date, we have not received final regulatory approval for any of our product candidates or derived any revenues from their sales. Moreover, there can be no assurance that we will ever receive regulatory approval for any of our product candidates or derive any revenues from their sales.

Our wholly-owned subsidiary, Zolovax, Inc. ("Zolovax"), is in preclinical studies to develop therapeutic and preventative medicines to treat infectious diseases based on our gp96 therapeutic technology, with a current focus on the development of a vaccine and diagnostic to target the SARS-CoV-2 coronavirus that causes COVID-19.

COVID-19 Diagnostic Development

We announced a research agreement with the University of Miami on March 23, 2020 to develop a simple, rapid, point-of-care and inexpensive paper-based test specific for 2019-nCoV. This is a non-PCR based rapid diagnostic test that utilizes a combination of reverse transcription recombinase polymerase amplification (RT-RPA) and a paper-based microfluidic analytical detection platform. This eliminates the need for high cost instrument and reagents used in PCR testing.

Recent Clinical Developments

In January 2019, we dosed our first patient in a Phase 2 clinical trial investigating HS-110 in combination with Merck's anti-PD1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab), in patients with advanced non-small cell lung cancer (NSCLC).

In February 2019, we announced updated interim results from our ongoing Phase 2 study of HS-110 in patients with advanced NSCLC. The results were presented at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium. Preliminary data suggests the addition of HS-110 to Nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy; equal survival was observed in patients with low CD8+ "cold" tumor at baseline compared to high CD8+ patients; and the occurrence of injection site reactions correlated with improved overall survival.

In June 2019, we announced new interim results from our ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®). The updated results were obtained from Cohort B patients whose data had matured an additional 3 months since last reported at the ASCO-SITC Clinical Immuno-Oncology Symposium in February of this year. This data may represent the first Phase 2 data showing clinical activity of a CPI combination in non-small cell lung cancer (NSCLC) patients whose disease has progressed after prior treatment with a checkpoint inhibitor (CPI). The Cohort B results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting poster session.

In July 2019, we announced we completed patient enrollment in our Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) or Merck's pembrolizumab (Keytruda®). The trial has completed enrollment with a total of 120 patients.

In August 2019, we announced that the FDA cleared the company's Investigational New Drug (IND) application to initiate a Phase 1 clinical trial of HS-130, in combination with HS-110, for patients with advanced solid tumors refractory to standard of care.

On November 5, 2019, an abstract titled "Treating Advanced Non-Small Lung Cancer Patients after Checkpoint Inhibitor Treatment Failure with a Novel Combination of Viagenpumatucel-L (HS-110) plus Nivolumab" which had been submitted by us to The Society for Immunotherapy of Cancer's (SITC) in connection with its 34th Annual Meeting was published by SITC. The data presented was obtained from an ongoing phase 2 study of previously treated non-small lung cancer patients (NSCLC) of HS-110 in combination with nivolumab (Cohort B). Patients in this cohort have progressed after ≥ 4 months of prior treatment with a checkpoint inhibitor. The study evaluates whether the addition of HS-110 to nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy. Cohort B data presented below is based on 56 patients in the intent-to-treat (ITT) population at the time of data cut-off:

- Response rate by RECIST 1.1
  - Partial response (PR) in 7 patients (13%)
  - Stable disease (SD) in 26 patients (46%)
  - Disease control rate (DCR) was (59%)

- Median overall survival (OS) was estimated at 11.8 months (95% CI; 6.6 – not reached months) with 39 of the 56 patients censored (70% of patients still alive).

- Median progression free survival (mPFS) was estimated at 3.2 months (95% CI; 1.9 - 4.0 months) with 17 patients censored.

- Subset analysis based on Injection Site Reaction (ISR):
  - Patients who experienced an ISR versus those who did not experience ISR:
    - Improved PFS (3.7 vs 1.8 months; HR 0.40, *p =0.0068*)
    - Improved OS (12 vs 5 months; HR 0.16, *p=0.0005*)

- Combination of HS-110 and nivolumab was well tolerated by patients.
  - 92% of adverse events (AEs) were mild (Grade 1 or 2).
  - There were only four grade 4 events, and no grade 5 AEs.

On November 19, 2019, members of our management team and certain clinical investigators in our ongoing Phase 2 study (Cohort A) of HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) presented a poster at the American Association for Cancer Research Special Conference on Tumor Immunology and Immunotherapy held in Boston, Massachusetts. Cohort A data presented below is based on the intent-to-treat (ITT) population at the time of data cut-off:

- Median Overall Survival of 16.9 months (50% of patients still alive with median follow up of 17 months)
  - Median overall survival of ISR positive patients was 42.1 months (95% CI; 15.8 – 42.1) vs. an ISR negative mOS of 5.9 months (95% CI; 1.4 – 11.6) (Hazard Ratio = 0.14, p <0.0001)
  - A prospectively defined analysis of PD-L1 negative vs. PD-L1 positive showed a difference in mOS of 16.9 months (95% CI; 5.5 - unk) to 42.1 months (95% CI; 1.6 - 42.1), respectively

- Objective Response Rate by iRECIST of 22% and DCR of 48%

- Tumor shrinkage in 46% of patients

- Patients who achieved stable disease or better showed statistically significant decreases in peripheral blood T cell subsets from baseline while on combination treatment

On December 16, 2019, we announced the dosing of the first patient in our first Phase 1 study of HS-130.

On March 2, 2020, we filed a provisional patent application that applies our immune system activating technology for treating or preventing infection with the *SARS-CoV-2* virus that causes coronavirus disease 2019 (COVID-19). An additional provisional patent application utilizing OX40L in combination with our gp96 platform for treating or preventing COVID-19 was also filed on March 2, 2020.

On March 3, 2020, we issued a press release announcing that we have formally launched a program to develop a vaccine using our immune activating gp96 vaccine platform for treating or preventing infection from the SARS-CoV-2 coronavirus that causes COVID-19.

On March 4, 2020, we entered into a collaboration with the University of Miami Miller School of Medicine to support the development of a vaccine leveraging our gp96 therapeutic technology designed to target the SARS-CoV-2 coronavirus that causes COVID-19

On March 20, 2020, we entered into a collaboration with the University of Miami to support the development of COVID-19 diagnostics.

The Oncology Market and Current Treatments

The American Cancer Society estimates that approximately 1.8 million people in the United States will be diagnosed with cancer in 2020. The lifetime probability of being diagnosed with cancer is approximately 50% for men and 50% for women. It is projected that 606,520 Americans will die from cancer in 2020.

Lung cancer is the second-most commonly diagnosed cancer in the U.S. The American Cancer Society estimates that there will be approximately 228,820 new cases of lung cancer in the United States diagnosed in 2020, accounting for about 13% of all cancer diagnosis. Despite continuous advances made in the field of cancer research every year, there remains a significant unmet medical need, as the overall five-year relative survival rate for lung cancer patients is 16% for men and 23% for women. Only 16% of lung cancers are diagnosed at a localized stage, for which the five-year survival is 57%. The American Cancer Society estimates that one in four deaths in the United States is due to cancer.

COVID-19

COVID-19 is a disease caused by a new kind of coronavirus (SARS-CoV-2) that first emerged in December 2019. The COVID-19 global pandemic affecting currently growing aggressively. 164 countries/regions around the world are affected, with a total of 266,115 confirmed cases with 11,153 deaths as of March 20, 2020 according to Johns Hopkins University of Medicine. Its economic impact is already more severe than SARS or MERS according to World Economic Forum. There is currently no treatment or vaccine for COVID-19.

2019 Financial Developments

- In November 2019, our CPRIT Grant, initially covering a period from June 1, 2016 through November 30, 2019, as amended, was extended to May 30, 2020.

***ImPACT*® /*ComPACT*℠ Platform Technology Advantages**

We seek to increase the percentage of patients with long-term benefit to checkpoint inhibitors with a combination treatment that is designed to activate and expand the T-cell's immune defense mechanisms to seek out and kill cancer cells. *ImPACT*® and *ComPACT*℠, variations of TCAP-based therapies, have been shown to stimulate an immune response based on a full antigenic repertoire of cancer cell associated proteins, not just one or a handful of antigens. The technologies are designed to combine a broad antigen repertoire of known tumor associated antigens, complexed with a potent immune adjuvant (gp96). The activated immune response generated by our TCAP-based therapies may be useful in treating a wide range of cancers and infectious diseases. The advantages include:

- *TCAP therapies are administered with checkpoint inhibitors and other immuno-modulators with the goal of enhancing immune response through T-cell activation.* Genetically engineered allogenic cells are injected into the dermal layers of the skin of patients to elicit an immune response against the patient's own tumor. The treatment primes immune recognition and triggers the body to stimulate a robust adaptive, T-cell mediated immune system to seek and destroy the cancer cells.

- *TCAP therapies are allogeneic, off-the-shelf treatments designed to activate the immune system to turn immunologically "cold" tumors "hot."* With *ImPACT*®, therapies can be administered alongside checkpoint inhibitors and other immuno-modulators to increase effectiveness. Our *ComPACT*℠ therapy combines antigen delivery and cross presentation with a highly selective T-cell co-stimulator within a single treatment, simplifying combination immunotherapy, while providing superior immune activation/expansion with reduced treatment costs.

- *Our "off-the-shelf," cancer-fighting therapies are designed to expand cancer reactive immune cells to recognize and kill cancer cells.* They jump-start immune recognition of common, cancer associated neo-antigens (proteins expressed normally in development prior to the upregulation of MHC expression) that are re-expressed in the cancer upon malignant transformation. When used alongside checkpoint inhibitors, they have been shown to boost T-cell activity to more effectively target and destroy cancer cells.

- *We don't require invasive procedures or the isolation of patient tissues.* We are not extracting anything from anyone. This eliminates the inconvenience and costs associated with securing, expanding, storing and transporting patient samples, while eliminating potential surgical risks.

- *Our therapies do not require an additional adjuvant, or immune stimulant.* Other immunotherapies may require the addition of an adjuvant to enhance effectiveness and reduce toxicity. Our product candidate incorporates gp96, itself a powerful biological adjuvant, ensuring that no additional immune adjuvants are necessary to generate an activated, T-cell mediated immune response.

- *Custom manufacturing is not necessary.* Our products are mass-produced and readily available for immediate patient use. Each patient receives the same treatment, offering logistical, manufacturing and other cost benefits, compared to patient-specific or "personalized" medicine approaches.

PTX-35/PTX-45 Advantages

The advantages include:

- Pelican provides access to a T-cell co-stimulator in two versions that further broadens our pipeline and strengthens our portfolio within the emerging T-cell co-stimulation space. We believe the use of these therapeutic agents, in combination with other immunotherapies, have the potential to be synergistic with our TCAP to dramatically improve patient outcomes.

- Pelican is the only company with a disclosed preclinical pipeline targeting the T-cell co-stimulator, TNFRSF25. We believe PTX-35 can activate antigen-specific memory CD8+ cytotoxic T-cells that has the potential to eliminate patient's tumor cells. This approach is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram and expand antigen experienced immunity, to support a long-term, durable therapeutic effect. When combined with immunotherapies, including the *ImPACT*® and *ComPACT*℠ platform technologies, PTX-35 enhances antigen specific T-cell activation to eliminate tumor cells.

- Preclinical studies with the murine precursor to PTX-35 show advantages over competing T-cell co-stimulator programs based on CD8+ T-cell specificity.

- PTX-45 is a human TL1A-Ig fusion protein that acts as an agonist of TNFRSF25 with many of the advantages of PTX-35 described above and a shorter *in vivo* half-life.

COVID-19 Vaccine Advantages

This is a potential first-in-class COVID-19 vaccine designed to generate long-term immune responses and may confer immunity to different coronaviruses. Our COVID-19 vaccine program is incorporating multiple SARS-CoV-2 antigens using our gp96 platform. We are mimicking the natural immune process to induce long-term immunity and to confer protection for individuals against future infections. In contrast to other vaccine approaches, our platform offers the following advantages:

- No anti-vector immunity given that we are not using a virus-based vector-system
- No viral activation as we do not utilize any attenuated virus
- Both T cells and B cells are activated with high immunogenicity to drive induction of mucosal immunity and long-term memory response

COVID-19 Diagnostic Advantages

The COVID-19 diagnostic test is a non-PCR based diagnostic test that utilizes a combination of reverse transcription recombinase polymerase amplification (RT-RPA) and a paper-based microfluidic analytical detection platform. This test targets to offer the following advantages compare to PCR-based diagnostics:

- Point-of-care test

- Rapid readout
- Does not require expensive instrument for analytical detection
- Cost-effective
- Selective and sensitive

Strategy

Our objective is to become a leading biopharmaceutical company specializing in the development and commercialization of allogeneic, “off-the-shelf” immunotherapies. *ImPACT*® and *ComPACT*™ are designed to address synergistic mechanisms of action: natural delivery of a robust repertoire of cancer associated antigens (CTAs) coupled with the activation, co-stimulation and expansion of cancer-specific killer T-cells to further enhance patients’ immune activity and immune memory. Pelican’s lead compound, PTX-35, is a humanized affinity matured TNFRSF25 agonist antibody, and potential best-in-class T-cell co-stimulator due to its preferential antigen specific memory CD8+ T-cells that are considered most potent in eliminating cancer cells. Preclinical studies with systemically administered PTX-35 show advantages over competing T-cell co-stimulator programs. In addition, Pelican is the only company with a disclosed program targeting TNFRSF25 for use in immuno-oncology, with a broad, pioneering intellectual property estate.

We believe future cancer immunotherapies will involve multiple agents and our platforms could work synergistically with therapies, such as checkpoint inhibitors, which are designed to reverse tumor-induced immune exhaustion and suppression. We are focused on discovering, developing, and applying the *ImPACT*® and *ComPACT*™ platform technologies, and our PTX-35/PTX-45 compounds in combination with other immunotherapies towards a number of disease indications. The key elements of our strategy are:

- *Develop and obtain regulatory approval for our product candidates*. We have completed enrollment of the HS-110 trial in combination with either nivolumab or pembrolizumab to treat patients with advanced NSCLC. Beyond NSCLC – depending upon funding and partnering opportunities – we plan to initiate new clinical trials of combined immunotherapy agents.

- *Maximize commercial opportunity for the ImPACT® and ComPACT™ technology, as well as our PTX-35 and PTX-45 compounds*. Our current product candidates target large markets with significant unmet medical needs. For each of our product candidates, we seek to maximize the economic potential of any future U.S. or international commercialization efforts.

- *Enhance our partnering efforts*. We are continually exploring partnerships for licensing and other collaborative relationships for Heat and Pelican and remain opportunistic in seeking strategic partnerships that maximize Heat’s economic potential.

- *Further expand our broad patent portfolio*. We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to do so. We have obtained exclusive rights to six different patent families directed to therapeutic compositions and methods related to our platform and preclinical development programs for cancer, and have filed additional patent applications that are owned by us. The *ImPACT*®/*ComPACT*™ patent portfolio comprise more than 20 granted patents and 25 pending patent applications. These patents and applications cover the United States, Europe, and Japan, as well as several other countries having commercially significant markets. In total, Pelican holds approximately 45 granted U.S. and foreign patents and approximately 30 U.S. and foreign patents are pending.

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

· *Obtain additional non-dilutive grant funding in addition to Pelican's $15.2 million CPRIT Grant*. To more fully develop our technologies and compounds, and their application to a variety of human diseases, we plan to continue to seek and access external sources of grant funding on our own behalf and in conjunction with our academic and other partners, including retention of lobbyists, 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.

Pelican Acquisition

On April 28, 2017, we consummated the acquisition of 80% of the outstanding equity of Pelican, a related party, and Pelican became our majority owned subsidiary as contemplated by the Stock Purchase Agreement (the "Purchase Agreement") that we entered into with Pelican, and certain stockholders of Pelican holding a majority of the outstanding shares.

Pelican is a biotechnology company focused on the development and commercialization of monoclonal antibody and fusion protein-based therapies that are designed to activate the immune system. In exchange for 80% of the outstanding capital stock of Pelican on a fully diluted basis, we paid to the Pelican Stockholders that executed the Stock Purchase Agreement (the "Participating Pelican Stockholders") an aggregate of $0.5 million minus certain liabilities (the "Cash Consideration"), and issued to the Participating Pelican Stockholders 133,106 shares of our restricted common stock representing 4.99% of the outstanding shares of our common stock on the date of the initial execution of the Purchase Agreement (the "Stock Consideration"). The Pelican Stockholders that sold their shares in Pelican to us (the "Participating pelican Stockholders") included Jeffrey Wolf, our Chief Executive Officer and a director, John Monahan and Edward Smith, two of our directors, the Chairman of our Scientific Advisory Committee at the time of the closing and/or entities controlled by them. During the year ended December 31, 2018, the Cash Consideration of approximately $0.3 million was distributed to the Participating Pelican Stockholders and the remainder of approximately $0.2 million for certain Pelican liabilities not satisfied was retained by us and recognized as other income in the Consolidated Statements of Operations and Comprehensive Loss.

Under the Purchase Agreement, we are also obligated to make future payments based on the achievement of certain clinical and commercialization milestones, as well as low single digit royalty payments and payments upon receipt of sublicensing income:

(1) $2.0 million upon Pelican's dosing of the first patient in its first Phase 1 trial for an oncology indication;
(2) $1.5 million upon Pelican's dosing of the first patient in its first Phase 2 trial for an oncology indication;
(3) $3.0 million upon successful outcome of the first Phase 2 trial for an oncology indication;
(4) $6.0 million upon Pelican's dosing of the first patient in its first Phase 3 trial for an oncology indication;
(5) $3.0 million upon Pelican's dosing of the first patient in its first Phase 3 trial for a non-oncology indication;
(6) $7.5 million upon successful outcome of the first Phase 3 trial for an oncology indication;
(7) $3.0 million upon successful outcome of the first Phase 3 trial for a non-oncology indication;
(8) $7.5 million upon acceptance of a Biologics License Application (BLA) submission for an oncology indication;
(9) $3.0 million upon acceptance of a BLA submission for a non-oncology indication;
(10) $7.5 million upon first product indication approval in the United States or Europe for an oncology indication; and
(11) $3.0 million upon first product indication approval in the United States or Europe for a non- oncology indication.

Pelican has been awarded $15.2 million to fund preclinical and some clinical activities from Cancer Prevention Institute of Texas (CPRIT) grant (the "CPRIT Grant"). The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT, which totals $7.6 million over the life of the project.

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

In October 2018, we entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of Pelican stock, of which it owned 5% equity on a fully diluted basis for a certain number of shares along with UM shares in Heat Biologics I, Inc., of which it owned 7.5% equity (together herein the "Subsidiary Shares") for 35,000 shares of Heat Biologics, Inc. common stock, $0.0002 par value; resulting in Heat owning 85% of Pelican and 100% of its subsidiary Heat Biologics I.

CPRIT Grant

In May 2016, Pelican was awarded a $15.2 million CPRIT Grant from CPRIT for development of Pelican's lead product candidate, PTX-35. The CPRIT Grant is expected to allow Pelican to develop PTX-35 through a 70-patient Phase 1 clinical program. The Phase 1 clinical program will be designed to evaluate PTX-35 in combination with other immunotherapies. The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT. Consequently, Pelican is required to raise $7.6 million in matching funds over the life of the project.

As of December 31, 2019, CPRIT has provided $13.7 million of the total $15.2 million grant. The remaining $1.5 millionwill be awarded after we have fulfilled every requirement of the grant and the grant has been approved to be finalized, rather than in advance of expending the funds as in the prior grant years. As of December 31, 2019, we have provided approximately $5.2 million which was used to satisfy Pelican's matching fund obligation under the first three years of the CPRIT Grant. Approximately $2.4 million is remaining to provide in the fourth year of the CPRIT grant.

The CPRIT Grant, as is customary for all CPRIT awards, contains a requirement that Pelican pay CPRIT a royalty on sales of commercial products developed using CPRIT funds equal to between three and five percent of revenue until such time as CPRIT has been paid an aggregate amount equal to 400% of the grant award proceeds. After 400% of the grant award proceeds has been paid, Pelican will pay CPRIT a royalty of 0.5% in perpetuity. After the CPRIT Grant terminates, Pelican is not permitted to retain any unused grant award proceeds without CPRIT's approval, but Pelican's royalty and other obligations, including its obligation to repay the disbursed grant proceeds under certain circumstances, to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and Pelican's obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect of our CPRIT project take place in Texas, survive the termination of the agreement. In addition, if Pelican relocates its principal place of business outside of Texas within the three year period after the date of final payment of grant funds (which final payment has not yet occurred), we are required to repay to CPRIT all grant funds received. Pelican expects to have received and expended all of the grant award proceeds by the agreement termination date.

The CPRIT Grant is subject to Pelican complying with all terms set forth in the CPRIT Grant, including Pelican maintaining its status with CPRIT as a Texas-based entity. In order to qualify as a Texas-based entity, a company must fulfill a majority of the following seven requirements: (i) its US headquarters must be physically located in Texas; (ii) its chief executive officer must reside in Texas; (iii) a majority of its personnel, including at least two other senior-level employees, must reside in Texas; (iv) its manufacturing activities must take place in Texas; (v) at least 90% of its grant award funds must be paid to individuals and entities in Texas, including salaries and personnel costs for employees and contractors: (vi) at least one clinical trial site must be in Texas; and (vii) it must collaborate with a medical research organization in Texas, including a public or private institution of higher education. Currently, Pelican meets a majority of these seven requirements.

Intellectual Property

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

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.

The Heat and Pelican programs are supported by growing patent estates that are comprised of intellectual property owned by Heat or Pelican, or exclusively licensed from UM. *ImPACT*®, *ComPACT*℠, PTX-45 (next generation improvements over PTX-15), and PTX-35 are protected by issued patents and various pending patent applications. In total, Heat holds approximately 20 granted U.S. and foreign patents and approximately 25 U.S. and foreign patents pending. In total, Pelican holds approximately 45 granted U.S. and foreign patents and approximately 30 U.S. and foreign patents are pending.

Heat's *ImPACT*® coverage is found in: the "Allogeneic Cancer –Based Immunotherapy" patent family patented in the US (US Patent Nos. 8,475,785 and 9,238,064), Europe, Israel, Australia and Canada and the "Heat Shock Protein GP96 Vaccination and Methods of Using Same" patent family, which is granted in the US (US Patent No. 8,968,720). Both of these patent families are subject to exclusive license agreements with UM and provide protection to 2029 (not including any patent term adjustments or extensions). Various recently filed provisional and international (PCT) patent applications assigned to Heat and relating to *ImPACT*® are also pending.

Heat's *ComPACT*℠ technology is covered by US Patent No. 10,046,047 and a series of patents pending in the U.S. and foreign jurisdictions (i.e. Europe, Japan, China, Canada, Australia, Brazil, Mexico, Israel, India, Korea, Russia, Singapore and South Africa) and assigned to Heat. Various recently filed provisional and international (PCT) patent applications assigned to Heat and related to *ComPACT*℠ are also pending and may provide coverage to 2038 or 2039.

Pelican's PTX-45 (next generation improvements over PTX-15) and PTX-35 coverage stems from three exclusive license agreements with UM (i.e. "UM03-31 UM05-39" of July 11, 2008; "UMI176" of December 12, 2010; and "UM-143 UMN-106" of November 19, 2013). Patents are granted or pending in the U.S. and various foreign jurisdictions (such as Europe, Japan, China, Canada, Australia, Mexico, Korea, Israel, Singapore, and Hong Kong). US Patent No. 9,603,925, with term to 2034 (not including any patent term adjustments or extensions), covers PTX-45 compositions in combination with additional therapies. US Patent No. 9,499,627, with term to 2030 (not including any patent term adjustments or extensions), covers PTX-45 uses in therapies to delay transplant rejections. US Patent No. 9,839,670, with term to 2026 (not including any patent term adjustments or extensions), covers PTX-35 compositions in combination with a tumor antigen. US Patent No. 9,017,679 with term to 2026 (not including any patent term adjustments or extensions), covers methods of using PTX-35, among other things. Recent patent applications assigned to Pelican are intended to provide further compositional coverage for PTX-35. US Patent Nos. 9,982,057 and 10,005,843 provide composition of matter coverage for PTX-35 and have term to 2035 (not including any patent term adjustments or extensions).

Heat's COVID-19 (2019-nCoV virus) efforts are supported by three patent applications. The Company co-owns two provisional patent applications, with University of Miami, on a vaccine approach and is the optionee to a US non-provisional application owned by the University of Miami on a point-of-care diagnostic test.

License Agreements

The “Modified Heat Shock Proteins-Antigenic Peptide Complex” patent family is licensed pursuant to the terms of an exclusive license agreement that was entered into by Heat in July 2008 and subsequently assigned to our subsidiary Heat Biologics I, Inc. which issued to UM shares of its common stock representing seven and one-half percent (7.5%) of its common stock, of which UM transferred to Heat in exchange for shares of our common stock in October 2018. 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 patent-related rights. As consideration for the rights granted in the license agreement, Heat Biologics I, Inc. was obligated to pay the University an upfront license fee of $150,000, additional yearly payments initially of $10,000 that increased to $20,000 in 2013 and a milestone payment of $500,000 upon approval of a BLA for the lung cancer vaccine covered by the patents rights being licensed.

The “Allogeneic Cancer-Based Immunotherapy” patent family is licensed to Heat Biologics I, Inc. pursuant to the terms of an exclusive license agreement that was entered into with UM in February 2011and the “Heat Shock Protein GP96 Vaccination and Methods of Using Same” patent family is licensed to Heat Biologics 1, Inc. pursuant to the terms of an exclusive license agreement that was also entered into with UM in February 2011. No upfront, annual or milestone payments are required to be paid to the University under either of these license agreements. The license agreements grant Heat Biologics I, Inc. exclusive, worldwide rights to make, use or sell licensed materials based upon the patent-related rights.

As consideration for the rights granted in each of these three license agreements,Heat Biologics I, Inc. is obligated to pay royalties 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 UM equal to a percentage of sublicense income. 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 UM is required to sell products covered by the licensed patent-related rights.

All of the above-described license agreements provide that the licensor has the right to terminate a subject license if the licensee: (1) has not introduced, or at least used its best efforts to introduce, a licensed product in the commercial marketplace in the United States, European Union, or Japan by December 31, 2020; (2) has not otherwise exercised diligence to bring licensed products to market; or (3) 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 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 UM. 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 UM for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

In July 2011, we exercised an option agreement with the University of Michigan (“U.Mich”) and entered into a license agreement with U.Mich pursuant to which we are U.Mich’s exclusive licensee and have the right to use, market, offer for sale, sell and/or sublicense materials and processes related to certain cancer cell lines. The term of the license is perpetual, unless terminated earlier by us or by U.Mich where U.Mich can only terminate for our material breach of this agreement. As consideration for the rights granted in the license agreement, we agreed to pay U.Mich up-front license fees and additional yearly and milestone payments. We also assumed under the license agreement responsibility for any infringement of third party rights caused by our use of the licensed materials. We paid an option fee of $2,000, a license issue fee of $10,000 and are obligated to pay an annual maintenance fee of $10,000 each year until the first commercial sale of a licensed product at which time the annual maintenance fee increases to $50,000. In addition, we are obligated to make milestone payments of $25,000, $50,000 and $75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial using a licensed product 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 agreement provides that the licensor has the right to terminate the license should we cease to carry on our business, fail to make a required payment or otherwise materially breach or default in our obligations under the license agreement following the giving of notice and an opportunity to cure any such breach. 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 October 2016, our wholly-owned subsidiary, Zolovax, Inc., entered into an agreement with UM for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases. The preclinical studies using the licensed technology have been initiated and are progressing. The term of the license is the length of the last to expire patent, unless terminated earlier. The license agreement grants Zolovax, Inc. exclusive, worldwide rights to make, use or sell licensed materials based upon the patent-related rights. As consideration for the rights granted in this license agreement, the licensee paid an upfront fee, is obligated to pay annual payments commencing on the third anniversary of the license agreement and royalties 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, Zolovax, Inc. is obligated to pay royalties to UM equal to a percentage of sublicense income. The license agreement provides for diligence milestones payments of up to an aggregate of $1,450,000 that include pre-IND meeting with the FDA, IND submission to the FDA and dosing first patient in a Phase 1 clinical trial. The license agreement also provides that the licensee will not have to pay more than the above-noted royalty rates if more than one license from UM is required to sell products covered by the licensed patent-related rights. The license agreement provides that the licensor has the right to terminate a subject license if the licensee has engaged in certain bankruptcy events or has breached the terms of the license agreement which includes having (i) failed to make a required payment; (ii) failed to achieve a milestone or not otherwise exercised diligence to bring licensed products to market; (iii) failed to possess insurance coverage, or (iv) filed a false report. Upon an uncured material breach of an obligation that remains uncured for 30 days' after notice thereof, the other party has the right to terminate that agreement. In March 2020, we entered into a research agreement with UM pursuant to which we sponsor the research and development of COVID-19 vaccine using our gp96 platform and a research agreement with UM for the development of a COVID-19 diagnostic test.

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

Pelican License Agreements

Under license agreements with UM, Pelican has obtained exclusive rights to six different patent families each directed to therapeutic compositions and methods related to targeting TNFRSF25/TL1A for the purpose of modulating immune responses. These families comprise approximately 45 granted U.S. and foreign patents, and approximately 30 U.S. and foreign patent applications. These patents and applications cover the United States, Europe and Japan as well as several other countries having commercially significant markets. As partial consideration for the initial two license agreements with UM, Pelican issued UM 300,000 shares of its common stock of which UM transferred to Heat in exchange for shares of our common stock in October 2018.

As consideration for the rights granted under the initial license agreement, UM-143 and UMN-106 non-oncology, Pelican is obligated to pay UM certain upfront license fees and milestone payments of ((i) $25,000 upon submission of an IND, (ii) $25,000 upon approval of an IND, (iii) $100,000 upon completion of a Phase 1 clinical trial and (iv) $250,000 the earlier of May 2022 or approval of a NDA), an annual minimum royalty payment $20,000 and royalties (mid-range single digits) based on net sales on commercialized products covered by the patent-related rights set forth above.

As consideration for the rights granted under the second license agreement, UMI-176 non-oncology, Pelican is obligated to pay UM certain upfront license fees, and aggregate milestone payments of (i) $25,000 upon submission of an NDA, (ii) $25,000 upon approval of a NDA; (iii) $100,000 upon completion of Phase 1 clinical trial and (iv) $500,000 the earlier of May 2022 or approval of an NDA), an annual minimum royalty payment $20,000 and royalties (mid-range single digits) based on net sales on commercialized products covered by the patent-related rights set forth above.

As consideration for the rights granted in the third license agreement, UM03-31 and UM05-39, Pelican is obligated to pay UM certain upfront license fees, past and future patent costs, an annual minimum royalty payment $20,000 and royalties (mid-range single digits) based on net sales on commercialized products covered by the patent-related rights set forth above. The third license agreement with UM provides that in the event that Pelican terminates its second license agreement with UM, Pelican is obligated to pay UM an annual minimum royalty payment of $20,000 for each year after 2014 during the term of the third license agreement as well as the following milestone payments: (i) $25,000 upon submission of an IND; (ii) $25,000 upon approval of a NDA; (iii) $100,000 upon completion of a Phase 1 clinical trial; and (iv) $250,000 the earlier of May 31, 2022 or approval of a NDA. The 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, Pelican is obligated to pay royalties to UM equal to a percentage of sublicense income. The third license agreement also provides that Pelican will not have to pay more than above royalty rates and sublicense fees if more than one license from UM is required to sell products covered by the licensed patent-related rights.

All of the above-described Pelican license agreements provide that the licensor has the right to terminate a subject license if the licensee (1) has not introduced, or at least used its best efforts to introduce, a licensed product in the commercial marketplace in the United States, European Union, or Japan by December 31, 2022 (December 2020 for the November 2013 license agreement); (2) has not otherwise exercised diligence to bring licensed products to market; or (3) 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 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 UM. In the event of a termination, Pelican 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 UM for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

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 utilized an external vendor for manufacturing of HS-110 used in our Phase 2 clinical trial and do not currently have a definitive agreement with any third-party vendors for the manufacture of additional quantities of HS-110.

The HS-110 product used in the inventor's Phase 1, and in our Phase 2 clinical trial was manufactured under cGMP (current good manufacturing practices). The TCAP cell line is grown in large quantities, dispensed into individual doses, frozen in liquid nitrogen, irradiated to render cell replication incompetent and quality tested in compliance with FDA guidelines. The product is irradiated, which is a commonly used attenuation process that eliminates the ability of the gp96-Ig-containing cell lines to replicate but allows them to remain metabolically active and secrete gp96-Ig. The batches of frozen, irradiated drug product are stable for long periods of time and are thawed immediately prior to administration to patients

Heat has also begun development of an additional product, HS-130, for treatment of select solid tumors. This product will utilize our *ComPACT*℠ technology concept, which is designed to deliver the gp96 heat shock (HS-110) protein and a T-cell co-stimulatory fusion protein (OX40L) in HS-130. We have completed the cGMP manufacturing and nonclinical IND enabling activities to support the clinical development of this product. This product is currently being used in a Phase 1 clinical trial.

Pelican is focused on the development of monoclonal antibody and fusion-protein based therapies designed to activate specific T-cell subsets of the immune system. We have utilized an external vendor for development of PTX-35, a humanized affinity matured monoclonal antibody that is a functional agonist of human TNFRSF25. This antibody provides highly selective and potent stimulation of 'memory' CD8+ cytotoxic T-cells. This is a subset of the class of T-cell that is responsible for eliminating tumor cells in patients. Pelican is in the process of completing the required product development and nonclinical IND enabling activities to support the clinical development of PTX-35.

Competition

The pharmaceutical, biologics and the diagnostic industry is highly competitive and characterized by a number of established large companies, and mid-sized companies, as well as smaller companies like ours. If our competitors' market products that are less expensive, safer or more effective than any future products developed from our product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to our research and development activities. As a biotechnology company with cancer immunotherapy agents as lead product candidates, we compete with a broad range of companies. At the highest level, cancer immunotherapy can be seen as both a complement and a potential competitor to any oncology therapy, most notably chemotherapy, radiotherapy, biologics and small molecule drugs. Not only do we compete with companies engaged in various cancer treatments including radiotherapy and chemotherapy, but we also compete with various companies that have developed or are trying to develop immunology vaccines for the treatment of cancer. Certain of our competitors have substantially greater capital resources, large customer bases, broader product lines, sales forces, greater marketing and management resources, larger research and development staffs with extensive facilities and equipment than we do and have more established reputations as well as global distribution channels. Our most significant competitors, among others, are fully integrated pharmaceutical companies such as Eli Lilly and Company, Bristol-Myers Squibb Company, Merck & Co., Inc., Novartis AG, MedImmune, LLC (a wholly owned subsidiary of AstraZeneca plc), Johnson & Johnson, Pfizer Inc., MerckKGaA and Sanofi SA, and more established biotechnology companies such as Genentech, Inc. (a member of the Roche Group), Amgen Inc., Gilead Sciences, Inc. and its subsidiary Kite Pharma, Inc., and competing cancer immunotherapy companies such as, Bluebird Bio, Inc., Transgene SA, Bausch Health Companies, NewLink Genetics Corporation, Agenus Inc., Aduro Biotech, Inc., Advaxis, Inc., ImmunoCellular Therapeutics, Ltd., IMV Inc., Oxford BioMedica plc, Bavarian Nordic A/S, Celldex Therapeutics, Inc., and others, some of which have substantially greater financial, technical, sales, marketing, and human resources than we do. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are less expensive, safer or more effective than those being developed by us or that would render our technology obsolete. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches.

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

- develop and market products that are less expensive, more effective or safer than our future products;
- commercialize competing products before we can launch any products developed from our product candidates;
- operate larger research and development programs, possess greater manufacturing capabilities or have substantially greater financial resources than we do;

- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled technical and scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

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

The primary treatments for non-small cell lung cancer are surgery, radiation, chemotherapy, checkpoint inhibitors, targeted therapies 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: Opdivo® (nivolumab), Keytruda® (pembrolizumab), Alimta® (pemetrexed), Avastin® (bevacizumab), Tarceva® (erlotinib), Gemzar® (gemcitabine), Paraplatin® (carboplatin), Taxol® (paclitaxel), Taxotere® (docetaxel), and Navelbine® (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 possible that HS-110 would be preferred both by physicians and patients in this stage of disease.

Our strategy is to emphasize what we believe to be our competitive advantages, which our products in development are expected to have less side effects than most other cancer therapies, be available at lower prices than other therapies, and ultimately could work on many types of cancer and not just one specific type.

Government Regulation

FDA Approval Process

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

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

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

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

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) 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 (3) 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 evaluate the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product’s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding $2.5 million, and the manufacturer and/or sponsor under an approved new drug application are also subject to an annual program fee which is currently set at more than $325,000. These fees are typically increased annually.

The FDA undertakes to perform an initial filing review within 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 nine months depending on the type of information included.

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

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

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

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.

Cell and Tissue-Based Biologics

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

Cell and tissue-based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use. Products manufactured using the *ImPACT*® technology meet this threshold and therefore are considered biological drugs. Manufacture of *ImPACT*® products are subject to both cGTP and cGMP regulations for manufacturing quality. Marketing of these products in the United States will require FDA approval under the BLA pathway as discussed above.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of HIPAA, as amended by HITECH, and similar state laws, each as amended.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act., as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; making a false statement or record material to payment of a false claim; or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the HITECH Act, and their respective implementing regulations. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include health care providers, health plans, and healthcare clearinghouse, that create, receive, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in specified circumstances, some of which are more stringent and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Additionally, the Federal Physician Payments Sunshine Act under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid, or CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, we may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost- effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidate for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. It is unclear how these challenges and other efforts to repeal and replace the ACA will impact our business in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Non-U.S. Regulation

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

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level; however, the centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. There can be no assurance that the chosen regulatory strategy will secure regulatory approval on a timely basis or at all.

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

Research and Development

We have built an internal and external research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical chemistry, manufacturing, clinical development and regulatory and quality assurance. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Our cancer trials have been registered on clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development. Research and development expenses were $13.0 million and $16.2 million during the years ended December 31, 2019 and 2018, respectively.

Emerging Growth Company

As of January 1, 2019, we were no longer an emerging growth company under the Jumpstart Our Business Startups Act enacted in April 2012 (“JOBS ACT”).

As an emerging growth company, we were subject to reduced public company reporting requirements and were exempt from Section 404(b) of Sarbanes Oxley. Section 404(a) requires issuers to publish information in their annual reports concerning the scope and adequacy of the internal control structure and procedures for financial reporting. This statement shall also assess the effectiveness of such internal controls and procedures. Section 404(b) requires that the registered accounting firm shall, in the same report, attest to and report on the assessment on the effectiveness of the internal control structure and procedures for financial reporting.

As an emerging growth company, we were also exempt from Section 14A(a) and (b) of the Exchange Act, which require stockholder approval, on an advisory basis, of executive compensation and golden parachutes.

Our Corporate Background and Information

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 627 Davis Drive, Suite 400, Morrisville NC 27560. 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 Business Conduct and Ethics and the Charters for the following Committees of the Board of Directors: Audit Committee, Compensation Committee, and Nominating Committee. Our phone number is (919) 240-7133 and our facsimile number is (919) 869-2128. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street NE, Room 1580 Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

References to Heat Biologics also include references to our subsidiaries Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd., Zolovax Inc., and Pelican, unless otherwise indicated. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. We formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012 and Heat Biologics Australia Pty LTD, a wholly-owned company, registered in Australia on March 14, 2014. On October 25, 2016, we formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, dengue, yellow fever, and SARS-CoV-2. In June 2012, we divested our 92.5% interest in Pelican (formerly known as Heat Biologics II, Inc.). On April 28, 2017, we completed the acquisition of an 80% controlling interest in Pelican, a related party prior to acquisition. In October 2018, we entered into an agreement with UM whereby UM exchanged its shares of stock in Heat's subsidiaries, Heat I, Inc. and Pelican, resulting in us owning 100% of Heat I, Inc. and increasing its controlling ownership inPelican from 80% to 85%. In November 2018, we formed two wholly-owned subsidiaries, Delphi Therapeutics, Inc. and Scorpion Biosciences, Inc. We assigned our proprietary rights related to the development and application of our *ImPACT*® therapy platform to Heat Biologics I, Inc.

We are also a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.

Employees

As of December 31, 2019, we had a total of 36 full-time employees. We believe our relationships with our employees are satisfactory. None of our employees is represented by a labor union. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel to pursue our development program. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.

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

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

Risks Relating to our Company

We have had limited operations to date.

We are a clinical stage company and have had limited operations to date as has our subsidiary, Pelican. 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. To date, we have not generated any revenue from product sales and our only revenue to date has been grant revenue that Pelican has received from CPRIT and a small amount of revenue from a research funding agreement. Even if we generate revenue from product sales, which is not anticipated for several years, if at all, there can be no assurance that we will be profitable. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise and cannot assure you that we will be able to successfully address these risks.

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

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

- continuing to undertake preclinical development and successfully enroll patients in clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

While various members of our management and staff have prior significant experience in conducting cancer trials, our company, to date, has not successfully completed any late stage clinical trials and we have limited experience conducting and enrolling patients in clinical trials. Until the last few years, our operations, including the operations of Pelican, have been limited primarily to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking preclinical trials and preparing for our early clinical and preclinical 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 have incurred net losses every year since our inception and expect to continue to generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.

For the years ended December 31, 2019 and 2018, we incurred a net loss of $20.4 million and $16.6 million, respectively. We have an accumulated deficit of $104.6 million through December 31, 2019. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. Our ability to achieve profitability will depend on us obtaining regulatory approval for our product candidates and market acceptance of our product offerings and our capacity to develop, introduce and sell our products to our targeted markets. There can be no assurance that any of our product candidates will be approved for commercial sale, or even if our product candidates are approved for commercial sale that we will ever generate significant sales or achieve profitability. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

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

- continue to undertake preclinical development and conduct clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses. As a result, we will need to generate significant revenues or raise additional financing in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would likely negatively impact the value of our securities and financing activities.

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

During the year ended December 31, 2019, our operating activities used net cash of approximately $12.8 million and as of December 31, 2019, our cash and cash equivalents and short-term investments were approximately $14.8 million. During the year ended December 31, 2018, our operating activities used net cash of approximately $21.7 million and as of December 31, 2018 our cash and cash equivalents and short-term investments were approximately $27.7 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2019, our accumulated deficit totaled $104.6 million and as of December 31, 2018, our accumulated deficit totaled $84.6 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive revenue from any significant source in the near future until we or our potential partners successfully commercialize our products. Despite cost-saving measures that we implemented, we expect our expenses to increase if and when we initiate and conduct Phase 3 and other clinical trials, and seek marketing approval for our product candidates. Until such time as we receive approval from the FDA and other regulatory authorities for our product candidates, we will not be permitted to sell our products and therefore will not have product revenues from the sale of products. For the foreseeable future, we will have to fund all of our operations and capital expenditures from equity and debt offerings, cash on hand, licensing fees and grants.

We will need to raise additional capital to fund our future operations and milestone payments and we cannot be certain that funding will be available to us on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which we expect will include sales of common stock through at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by our number of authorized shares of common stock and various rules of the SEC and the Nasdaq Capital Market that place limits on the number and dollar amount of securities that we may sell. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders, assuming we are able to sufficiently increase our authorized number of shares of common stock. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we fail to raise additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities or continue to maintain our listing on the Nasdaq Capital Market. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

Global health crises may adversely affect our planned operations.

Our business and the business of the supplier of our clinical product candidate and the suppliers of the standard of care drugs that are administered in combination with our clinical product candidate could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis, such as the recent outbreak of novel coronavirus (COVID-19). A significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect our planned operations. Such events could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of our clinical product candidate or the standard of care drugs that are administered in combination with our clinical product candidate. In addition, an outbreak near our clinical trial sites are located would likely impact our ability to recruit patients, delay our clinical trials, and could affect our ability to complete our clinical trials within the planned time periods. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

Coronavirus could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China. Since then, the COVID-19 coronavirus has spread to multiple countries, including the United States and European and Asia-Pacific countries, including countries in which we have planned or active clinical trial sites. As the COVID-19 coronavirus continues to spread around the globe, we will likely experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

In addition, the outbreak of the COVID-19 coronavirus could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. COVID-19 illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

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

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

Our audited financial statements for the fiscal year ended December 31, 2019 and were prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities. These factors raise substantial doubt about our ability to continue as a going concern for one year after the financial statements are issued. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to its technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms or at all, we may be unable to complete planned preclinical and clinical trials, or obtain approval of our product candidates from the FDA and other regulatory authorities.

We are substantially dependent on the success of our product candidates, only two of which are currently being tested in clinical trials, and we cannot provide any assurance that any of our product candidates will be commercialized.

Our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our product candidate, HS-110, for which we are currently actively conducting a Phase 2 clinical trial. HS-110 and HS-130 are our only current products in clinical trials. Our other product candidates are all at a pre-clinical stage. We expect that at least one Phase 3 clinical trial of HS-110 will be required to gain approval by the FDA. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize our product candidates, which may never occur. Before commercializing this 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 any of our product candidates, and we may never be able to develop or commercialize a marketable drug.

If our acquired intangible assets become impaired, we may be required to record a significant charge to earnings.

We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite-lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity-specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price. During the year ended December 31, 2019, we recorded a non-cash goodwill impairment charge of $737,000.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act.

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. As we seek to advance our clinical programs, we remain in close contact with our CROs and clinical sites and intend to monitor and assess the impact of COVID-19 on our studies, current timelines and the costs of our studies.. The rapid development and fluidity of this situation precludes any prediction as to the ultimate adverse impact to us of enrollment in clinical trials, and no assurance can be given that the impact of COVID-19 will not seriously disrupt our ability to enroll patients in our clinical trials.

Risks Relating to our Business

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

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

- prevent or delay commercialization of, and our ability to derive product revenues from, our product candidates; and
- diminish any competitive advantages that we may otherwise believe that we hold.

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

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

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

Our product candidates are in early stages of development, and therefore they will require extensive preclinical and clinical testing.

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. HS-110 and HS-130 are our only current product candidates in clinical trials and our other product candidates are all in the preclinical stage of development. Although we have completed enrollment for a Phase 2 clinical trial for HS-110 and a Phase 1 clinical trial of HS-130, we cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The results reported for our initial 76 patients in our Phase 1b/2 clinical trial for HS-110 or initial data in our Phase 2 clinical trial for HS-110 may not be replicated with other patients or other clinical trials. For example, the Phase 1 HS-410 clinical trial, as well as the interim data from the Phase 2 HS-410 clinical study, showed evidence of an immune response in NMIBC patients exposed to HS-410, however, the topline data from the Phase 2 clinical trial reported that there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. The Phase 2 clinical trial of HS-410 used doses and dosing regimens which had not previously been tested, and combinations with other immunotherapy agents. In addition, immune response is not an acceptable regulatory endpoint for approval, and the HS-410 Phase 1 trial involved a small sample size and was not randomized or blinded. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Our COVID vaccine and diagnostic test programs are in early stages of development, and therefore they will require extensive testing and funding.

We have initiated development of a new COVID-19 vaccine program that utilizes the gp96 platform to secrete SARS-CoV-2 antigens. In parallel, we, together with our collaborator, the University of Miami, are developing a COVID-19 point-of-care diagnostic test. Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. In addition, in order to further our COVID-19 vaccine program and diagnostic test we will need significant additional funding. To date, we have not yet developed any drug candidates designed to combat infectious diseases nor have we developed any diagnostic tests. There can be no assurance given that we will be able to successfully develop a vaccine to treat COVID-19 or a diagnostic test for COVID-19, and even if successful, to do so during this pandemic, or be able to secure the additional funding required to further our COVID-19 vaccine program and diagnostic test. Although we have retained consultants, including lobbyists, to seek funding for these new programs, there can be no assurance that we will be able to obtain such financing.

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

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

- unforeseen safety issues;
- failure to determine appropriate dosing;
- greater than anticipated cost of our clinical trials;
- failure to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment or difficulty obtaining investigators;
- patient drop-out or discontinuation;
- inability to monitor patients adequately during or after treatment;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;
- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;
- problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;
- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

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

We are at risk of a clinical hold at any time based on the evaluation of the data and information submitted to the governing regulatory authorities. On February 2, 2016, we received notice from the FDA of a partial clinical hold on our Phase 2 HS-410 clinical trial despite the fact that we did not have a safety concern. The partial clinical hold came after we concluded that the cell line on which HS-410 is based had been previously misidentified. The partial clinical hold was lifted on February 10, 2016. However, if in the future we are delayed in addressing, or unable to address, any FDA concerns, we could be delayed, or prevented, from conducting our clinical trials.

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

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

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

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

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

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

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

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

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

We have developed certain expertise in the formulation, development and/or manufacturing of biologics but do not intend to establish our own manufacturing facilities. To date, the selection and initial replication of our biological cell lines used in our trials has been performed by individuals working at third party laboratories over which we have little process or quality control and therefore the process and replication could be subject to human error. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational products for our clinical trials are manufactured by our contractors under current good manufacturing practices, ("cGMPs") and we have entered into agreements with commercial-scale manufacturers for the production and supply of investigational product for additional Phase 2 and Phase 3 clinical trials as well as commercialization. Our agreement with the manufacturer of our HS-110 product expired in October 2019, and we have no assurance that we can extend current agreement or renegotiate our agreement on favorable terms if at all. In addition, the manufacturer of our HS-110 has closed its facility where it manufactured our HS-110 and therefore future manufacture of HS-110 by such manufacturer may require additional regulatory approvals for the new manufacturing site. Any future orders with such manufacturer will be pursuant to the terms of purchase orders unless a new definitive agreement is entered into. If not renegotiated, we may experience longer manufacturing lead times for any purchase orders we place with either such manufacturer under purchase orders or any new manufacturer, especially in light of additional regulatory requirements due to the change in the manufacturing facility. Manufacturing considerations which may include, lead time and capacity considerations of our third-party manufacturers to provide clinical supply of our product candidates, could delay our clinical trials. 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 renew or renegotiate current agreements on favorable terms, or identify manufacturers on acceptable terms or at all because the number of potential manufacturers with appropriate expertise and facilities is limited.

- If we change manufacturers at any point during the development process or after approval, we will be required to demonstrate comparability between the products made by the old and new manufacturers. If we are unable to do so, we may need to conduct additional clinical trials with product manufactured by the new manufacturer. Accordingly, it may be necessary to evaluate the comparability of the HS-110 or other product candidates produced by the two different manufacturers at some point during the clinical development process.

- If we change the manufacturer of a product subsequent to the approval of the product, we will need to obtain approval from the FDA of the change in manufacturer. Any such approval would likely require significant testing and expense, and the new manufacturer may be subject to a cGMP inspection prior to approval. Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and with the quality required to meet our clinical needs and commercial needs, if any.

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

For 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 any of our third-party manufacturers were to experience any prolonged disruption for our manufacturing, we could be forced to seek additional third party manufacturing contracts, thereby increasing our development costs and negatively impacting our timeliness and any commercialization costs.

For our ongoing clinical trial of HS-110, we are administering our product candidates, in combination with other immunotherapy agents. Any problems obtaining the other immunotherapy agents could result in a delay or interruption in our clinical trials.

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

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

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

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

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

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

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

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

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

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

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates may increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

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

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

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

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

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

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

- developing drugs, biologics and other therapies;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs, biologics and other therapies;
- formulating and manufacturing drugs, biologics and other therapies; and
- launching, marketing and selling drugs, biologics and other therapies.

We have limited protection for our intellectual property, which could impact our competitive position.

We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have obtained exclusive rights to license the technology for which patent protection has been obtained; however, certain patents expired in 2019 and such protection does not prevent unauthorized use of such technology. In addition, our license for certain cell lines are subject to non-exclusive licenses and do not have patent protection. Trademark and copyright protections may be limited, and enforcement could be too costly to be effective. It may also be possible for unauthorized third parties to copy aspects of, or otherwise obtain and use, our proprietary information without authorization, including, but not limited to, product design, software, customer and prospective customer lists, trade secrets, copyrights, patents and other proprietary rights and materials. Other parties can use and register confusingly similar business, product and service names, as well as domain names, which could divert customers, resulting in a material adverse effect on our business, operating results and financial condition.

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

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

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

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

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

- abandon an infringing drug or therapy candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

For the years ended December 31, 2020, 2021, 2022, and 2023 our minimum annual payment obligations under our licensing agreements, (including the licenses that Pelican has entered into), required to be paid by us with the passage of time, are approximately $0.1 million, $0.2 million, $0.8 million and $0.07 million, respectively. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments or milestone payments owed to the Pelican Stockholders pursuant to the terms of the stock purchase agreement that we entered into with Pelican and certain stockholders of Pelican in March 2017. The license agreements also provide for certain developmental milestones, as does the purchase agreement that we entered into with Pelican and certain stockholders of Pelican in March 2017, including future payments to Pelican based on the achievement of certain milestones. No assurance can be given that we will meet all of the required developmental milestones or have sufficient funds to make required payments under the purchase agreement. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license and any failure to make payments under the purchase agreement would constitute a default under the purchase agreement. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

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

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

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our clinical product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, The Patient Protection and Affordable Care Act (ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (70% as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. It is unclear how these challenges and other efforts to replace the ACA will impact our business in the futures.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our clinical product candidate or additional pricing pressures. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We may not successfully effect our intended expansion, which would harm our business prospects

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. We currently operate one laboratory in North Carolina and Pelican operates a laboratory in Texas. In our laboratory in Texas we perform contract services for third parties that could involve the use of biological and hazardous materials and chemicals. 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 $2.0 million insurance policy we hold on the life of Jeffrey Wolf, we do not have "key person" life insurance policies for any of our officers or advisors. The loss of the technical knowledge, management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

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

We will need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. Over the next 12 months, we expect to hire additional new employees both in North Carolina and for Pelican in Texas. In fact, due to the CPRIT Grant and certain other funding we have received, we are required to hire employees located in Texas. 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 especially in light of the CPRIT Grant requirements, including the requirement that Pelican maintain its headquarters in Texas and use certain vendors, consultants and employees located in Texas. Attracting and retaining qualified personnel will be critical to our success.

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

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

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

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

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

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

- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors' activities.

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

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

As part of our business strategy, we may pursue acquisitions of businesses and assets, such as we did with the Pelican. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. Other than our acquisition of the equity of Pelican in 2017, we have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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

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

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. If the economic climate does not improve or continues to be uncertain, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

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

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

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

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

Neither we nor Pelican are expected to derive revenue from any source in the near future until we or they or other potential partners successfully commercialize products. The CPRIT Grant requires that Pelican provide matching funds for one half of the award amount in order for Pelican to receive the grant funding. In order to receive the full $15.2 million award over the life of the grant, Pelican must raise matching funds in the aggregate amount of approximately $7.6 million. CPRIT has made available to Pelican an aggregate of $13.7 million of grant funding through December 31, 2019 and Pelican has received funding from us to satisfy its related matching obligation of approximately $5.2 million. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our or Pelican's technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms or at all, we may be unable to complete planned preclinical and clinical trials, access the CPRIT award or obtain approval of our product candidates from the FDA and other regulatory authorities.

Reliance on government funding for Pelican's programs may impose requirements that limit Pelican's ability to take certain actions, and subject it to potential financial penalties, which could materially and adversely affect its business, financial condition and results of operations.

A significant portion of Pelican's funding has been through a grant it received from the CPRIT Grant. The CPRIT Grant includes provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event Pelican violates certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas. After the CPRIT Grant ends, Pelican is not permitted to retain any unused grant award proceeds without CPRIT's approval, but Pelican's royalty and other obligations, including its obligation to repay the disbursed grant proceeds under certain circumstances, , to maintain certain records and documentation, to notify CPRIT of certain unexpected adverse events and our obligation to use reasonable efforts to ensure that any new or expanded preclinical testing, clinical trials, commercialization or manufacturing related to any aspect to our CPRIT project take place in Texas, survive the termination of the agreement.

Pelican's award from CPRIT requires it to pay CPRIT a portion of its revenues from sales of certain products by it, or received from its licensees or sublicensees, at tiered percentages of revenue in the low- to mid-single digits until the aggregate amount of such payments equals 400% of the grant award proceeds, and thereafter at a rate of less than one percent for as long as Pelican maintains government exclusivity, subject to Pelican's right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to terminate such payment obligations. In addition, the grant contract also contains a provision that provides for repayment to CPRIT of some amount not to exceed the full amount of the grant proceeds under certain specified circumstances involving relocation of Pelican's principal place of business outside Texas.

The CPRIT Grant requires Pelican, as a Texas-based company, to meet certain criteria, including among other things, that Pelican maintain its headquarters in Texas and use certain vendors, consultants and employees that are located in Texas. If Pelican fails to maintain compliance with any such requirements that may apply to it now or in the future, it may be subject to potential liability and to termination of its contracts, including potentially the CPRIT Grant.

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

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

For the year ended December 31, 2018 we reported under 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 ceased to be an "emerging growth company" as defined in the JOBS Act, on December 31, 2018. However, for the year ended December 31, 2018, we were an emerging growth company. An "emerging growth company," as defined under the JOBS ACT, we could 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 audit rules adopted by the Public Company Accounting Oversight Board (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.

Under the JOBS ACT, a company is deemed 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 $1.07 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 $1.0 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 elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of the JOBS Act, that allowed us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Further, as a result of these scaled regulatory requirements, our disclosure while an emerging growth company may be more limited than that of other public companies and you may not have the same protections afforded to shareholders of such companies.

We ceased to be an "emerging growth company," which means we will no longer be able to take advantage of certain reduced disclosure requirements in our public filings.

We ceased to be an "emerging growth company," as defined in the JOBS Act, on December 31, 2018. As a result, our costs and compliance initiatives increased as a result of the fact that we ceased to be an "emerging growth company." In particular, we are now, or will be, subject to certain disclosure requirements that are applicable to other public companies that had not been applicable to us as an emerging growth company. These requirements include: compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting once we are an accelerated filer or large accelerated filer, compliance with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; and full disclosure and analysis obligations regarding executive compensation; and compliance with regulatory requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. However, our status as a smaller reporting company will not exempt us from the requirement to provide the annual attestation report from our independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all.

Risks Related to Our Common Stock

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

Our shares of common stock are currently listed on The Nasdaq Capital Market. If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, The Nasdaq Capital Market may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. In the past we have received notices from the Listing Qualifications Department of Nasdaq Stock Market LLC ("Nasdaq") that we failed to comply with the stockholder's equity requirements and the minimum closing bid requirements. On June 21, 2019, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that for the preceding 30 consecutive business days (May 9, 2019 through June 20, 2019), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). The notice has no immediate effect on the listing or trading of our common stock which will continue to trade on The Nasdaq Capital Market under the symbol "HTBX". In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we initially had a compliance period of 180 calendar days, or until December 18, 2019, to regain compliance with Nasdaq Listing Rule 5550(a)(2), which compliance period has been extended to June 15, 2020. Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of ten consecutive business days at any time during the compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed There can be no assurance can be given that we will be able to satisfy our continued listing requirements and maintain the listing of our common stock on The Nasdaq Capital Market. We intend to attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any action that requires stockholder approval will be approved by our stockholders or that any action taken by us would result in our common stock meeting the Nasdaq listing requirements, or that any such action would stabilize the market price or improve the liquidity of our common stock.

The possible issuance of common stock subject to options, restricted stock units and warrants may dilute the interests of stockholders.

As of March 23, 2020, awards for 7,586,555 shares of common stock are outstanding under our equity compensation plans and 2,343,512 shares of common stock remain available for grants under the plans. In addition, as of March 23, 2020, we have warrants exercisable for 9,322,398 shares of our common stock to third parties in connection with our public offerings. 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 certificate of incorporation, amended on March 20, 2020 to increase authorized common stock by 150,000,000, authorizes the issuance of 250,000,000 shares of our common stock and 10,000,000 shares of preferred stock. In certain circumstances, the common stock and preferred stock, as well as the awards available for issuance under the 2014, 2017, and 2018 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. Our board of directors is authorized to create and issue from time to time, only with stockholder approval, up to an aggregate of 10,000,000 shares of preferred stock of which 8,212,500 have been designated. The authority to designate preferred stock may be used to issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of the common stock or could also be used as a method of determining, delaying or preventing a change of control.

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.

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

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination, including mergers and asset sales, with an interested stockholder (generally, a 15% or greater stockholder) for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The operation of Section 203 may have anti-takeover effects, which could delay, defer or prevent a takeover attempt that a holder of our common stock might consider in its best interest. Certain provisions of our bylaws including the ability of our board of directors to fill vacancies on our board of directors and advance notice requirements for stockholder proposals and nominations may prevent or frustrate attempts by our stockholders to replace or remove our management. In addition, the Rights issued pursuant to our stockholder rights plan that we implemented, if not redeemed or suspended, could result in the dilution of the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors and therefore discouraging, delaying or preventing a change in control that stockholders may consider favorable.

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

On March 23, 2020, we had 79,384,021 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our stockholders might sell significant shares of our common stock could also depress the market price of our common stock.

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

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

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

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, the recent outbreak of the COVID-19 coronavirus has caused broad stock market and industry fluctuations. As a result of this volatility, investors in our common stock could incur substantial losses. In addition, sales of substantial amounts of our common stock, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short period of time. As a result, our stockholders could suffer losses or be unable to liquidate holdings.

In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

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

Our previously issued warrants may not have any value.

Our previously issued warrants to purchase shares of our common stock may not have any value. For example, we previously issued warrants in a public offering that have an exercise price of $10.00 per share. In the event that our common stock price does not exceed the exercise price of our previously issued warrants during the period when the warrants are exercisable, the warrants may not have any value.

There is no established market for the warrants that we previously issued.

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

The shares of common stock offered under any at the market offering that we may engage in, and investors who buy shares at different times will likely pay different prices.

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

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

Securities research analysts, including those affiliated with our underwriters from prior offerings, 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 to continue going forward, 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 need for future financing may result in the issuance of additional securities that will cause investors to experience dilution

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

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

None.

Item 2. ***Properties***

Facilities

Our executive offices are located at 627 Davis Drive, Suite 400, Morrisville, North Carolina 27560. In October 2019, we entered into lease that expires October 31, 2027 for 7,492 square feet of office and laboratory space for monthly rent of $17,013 exclusive of payments required for maintenance of common areas and utilities.

In January 2018, Pelican entered into a five-year lease for 5,156 square feet of office and laboratory space located San Antonio, Texas for monthly rent of $9,452, exclusive of payments required for maintenance of common areas and utilities.

Item 3. ***Legal Proceedings***

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

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

Not applicable.

PART II

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

Market Information

Our common stock has traded on theNasdaq Capital Market under the symbol "HTBX".

Holders

As of March 23, 2020, there were approximately 47 stockholders of record of our common stock.The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

On January 19, 2018, we announced a reverse stock split of our shares of common stock at a ratio of one-for-ten. The reverse stock split took effect at 11 P.M. EST on January 19, 2018, and our common stock began to trade on a post-split basis at the market open on January 22, 2018. During our special stockholders meeting held February 27, 2020, shareholders approved a proposal to effect a reverse stock split of the issued and outstanding shares of common stock, and granted the board of directors the authority to implement and determine the exact split ratio, if it still deems it advisable.

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, 2019.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2009 Stock Incentive Plan (1)	47,267	$ 12.71	—
2014 Stock Incentive Plan	225,063	$ 17.33	40,729

2017 Stock Incentive Plan	318,570	$	2.56	87,817
2018 Stock Incentive Plan (2) (3)	2,472,736	$	1.02	3,090,800
Equity compensation plans not approved by security holders	—		—	—
Total	3,063,636	$	2.56	3,219,346

(1) The 2009 Stock Incentive Plan terminated, such that no further awards are available for issuance under this plan. Outstanding awards under this plan continue in accordance with the respective terms of such grants.

(2) Represents options to purchase shares of our common stock. On January 1, 2019, we granted an aggregate of 1,579,179 shares of restricted stock to employees and a director, which are not included in column (a) above and are excluded from the number of shares available for future issuance in column (c) above. On December 30, 2019, we granted 900,000 shares of restricted stock which are not included in column (a) above and are excluded from the number of shares available for future issuance in column (c) above. Subsequent to December 31, 2019, we issued: (i) Jeffrey Wolf 1,980,000 restricted stock awards, respectively, that vested 50% on the grant date, with the remaining shares of restricted stock vesting 30% on the first anniversary of the grant date, 10% on the second anniversary of the grant date, and the remaining 10% vesting on the third anniversary of the grant date, (ii) John K.A. Prendergast, our lead independent director 400,000 restricted stock awards, respectively, that vested 50% on the grant date, with the remaining shares of restricted stock vesting 30% on the first anniversary of the grant date, 10% on the second anniversary of the grant date, and the remaining 10% vesting on the third anniversary of the grant date; (iii) stock option to purchase 150,000 shares of common stock to each of John Monahan and Edward B. Smith, III vesting 50% on the grant date, with the remaining shares vesting 30% on the first anniversary of the grant date, 10% on the second anniversary of the grant date, and the remaining 10% vesting on the third anniversary of the grant date, (iv) Dr. Jeff Hutchins, our Chief Scientific Officer and Chief Operating Officer and William Ostrander, our Vice President of Finance, stock options to purchase 500,000 and 150,000 shares of our common stock, respectively that vest prorate on a monthly basis over four years.

(3) In February 2020, our stockholders approved an amendment to the 2018 Stock Incentive Plan to increase the total number of shares of common stock available for grant under such plan by an additional 4,000,000 shares of common stock.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during the year ended December 31, 2019.

Purchase of Equity Securities

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

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

Not applicable because we are a smaller reporting company.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the years ended December 31, 2019 and December 31, 2018 found in this Annual 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 "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Report.

Company Overview

We are a biopharmaceutical company developing immunotherapies focused on activating a patient's immune system against cancer through T-cell activation and expansion. Our T-cell Activation Platform (TCAP), includes two variations for intradermal administration Immune Pan-antigen Cytotoxic Therapy (*ImPACT*®) and Combination Pan-antigen Cytotoxic Therapy (*ComPACT*™). To further augment antigen experienced T-cell activation and expansion, we are also developing a novel T-cell co-stimulator PTX-35 for systemic administration. These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We have completed enrolling patients in our HS-110 combination immunotherapy trial, preparing IND submissions for HS-130 and PTX-35 programs, and providing pre-clinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest.

We have completed the enrollment of our Phase 2 clinical trial for advanced non-small cell lung cancer (NSCLC), in combination with either Bristol-Myers Squibb's nivolumab (Opdivo®) or more recently, Merck's anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®). Our other programs (HS-130 and PTX-35) have completed pre-clinical and CMC development with one IND filing in 2019 (HS-130) and another anticipated in the second quarter of 2020.

Our T-cell Activation Platform (TCAP), includes a variation of two TCAPs, *ImPACT*® and *ComPACT*™ which are designed to activate and expand tumor antigen specific "killer" T-cells to destroy a patient's cancer. By turning immunologically "COLD tumors HOT," we believe our platform will become an essential component of the immuno-oncology cocktail to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

We believe the advantage of our approach is that our biologic agents deliver a broad range of tumor antigens that are unrecognized by the patient's immune system prior to the malignant rise of the patient's tumor. TCAP combines these tumor associated antigens with a powerful, naturally occurring immune adjuvant, gp96, to actively chaperone these antigens out of our non-replicating allogenic cell-based therapy into the local microenvironment of the skin. The treatment primes local natural immune recognition to activate T-cells to seek and destroy the cancer cells throughout the body. These TCAP agents can be administered with a variety of immuno-modulators to enhance a patient's immune response through ligand specific T-cell activation.

Unlike many other "patient specific" or autologous immunotherapy approaches, our drugs are fully-allogenic, "off-the-shelf" products which means that we can administer immediately without the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment based on these patient materials. Our TCAP product candidates from our *ImPACT*® and *ComPACT*™ platforms are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. Because each patient receives the same treatment, we believe that our immunotherapy approach offers superior speed to initiation, logistical, manufacturing and importantly, cost benefits, compared to "personalized" precision medicine approaches.

Our *ImPACT*® platform is an allogenic cell-based, T-cell-stimulating platform that functions as an immune activator to stimulate and expand T-cells. The key component of this innovative immunotherapy platform is the dual functionality of the heat shock protein, gp96.

As a molecular chaperone, gp96 is typically found within the cell's endoplasmic reticulum and facilitates the folding of newly synthesized proteins for functionalized tasks. But when a cell abnormally dies through necrosis or infection, gp96 is naturally released into the surrounding microenvironment. At this moment, gp96 becomes a Danger Associated Molecular Protein or "DAMP", a molecular warning signal for localized innate activation of the immune system. In this context gp96 serves as a potent adjuvant, or immune stimulator, via Toll-Like Receptor 4/2 (TLR4 and TLR2) signaling which serves to activate APCs to specialized dendritic cells that upregulate T-cell costimulatory ligands, MHC and immune activating cytokine. It is among the most powerful adjuvants found in the body and uniquely shows exclusive specificity to CD8+ "killer" T-cells through cross-presentation of the gp96-chaperoned tumor associated peptide antigens directly to MHC class I molecules for direct activation and expansion of CD8+ T-cells. Thus, gp96 plays a critical role in the mechanism of action for Heat's T-cell activating platform immuno-therapies; mimicking necrotic cell death and activating a powerful, tumor antigen-specific T-cell immune response to attack the patient's cancer cells.

ComPACT℠, our second TCAP, is a dual-acting immunotherapy designed to deliver antigen driven T-cell activation and specific co-stimulation in a single product. *ComPACT*℠ helps unlock the body's natural defenses and builds upon *ImPACT*® by providing specific co-stimulation to enhance T-cell activation and expansion. It has the potential to simplify combination immunotherapy development for oncology patients, as it is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) as a single therapeutic, without the need for multiple, independent biologic products. The potential advantages of *ComPACT*℠ include: (a) enhanced activation of antigen-specific CD8+ T-cells; (b) serving as a booster to expand the number of antigen-specific CD8+ T-cells compared to OX40L alone; (c) stimulation of T-cell memory function to remain effective in the body after treatment, even if the cancer comes back; (d) demonstration of less toxicity, as the source of cancer associated antigens and co-stimulator are supplied at the same time locally and the draining lymph nodes, which drive targeted, cancer specific immunity towards the tumor rather than throughout the body; and (e) a potential paradigm shift that is designed to simplify combination cancer immunotherapy versus systemic co-stimulation with conventional monoclonal antibodies (mAbs).

Pelican, our subsidiary, is a biotechnology company focused on the development of biologic based therapies designed to activate the immune system, including the monoclonal antibody, PTX-35. PTX-35, which is currently focused on preclinical IND enabling activities, is Pelican's lead product candidate targeting the T-cell co-stimulator, TNFRSF25. It is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. TNFRSF25 agonism has been shown to provide highly selective and potent stimulation of antigen experienced 'memory' CD8+ cytotoxic T-cells, which are the class of long-lived T-cells capable of eliminating tumor cells in patients. Due to the preferential specificity of PTX-35 to activate antigen experienced CD8+ T-cells, this agent represents a promising candidate as a T-cell co-stimulator in cancer patients.

When combined in preclinical studies with *ImPACT*® and *ComPACT*℠ platform immunotherapies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target TNFRSF25 for various immunotherapy approaches, including PTX-45, a human TL1A-lg fusion protein designed as a shorter half-life agonist of TNFRSF25.

We continue to enroll patients in our HS-110 combination immunotherapy trial, preparing for IND submission of HS-130 (*ComPACT*℠), advancing pre-clinical development of Pelican assets in anticipation of an IND submission, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue since our inception and no revenue from product sales. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

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

2019 Financial Developments

- In November 2019, our CPRIT Grant, initially covering a period from June 1, 2016 through November 30, 2019, as amended, was extended to May 30, 2020.

Funding/Liquidity

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 primarily financed our operations with net proceeds from the sale of our securities including, our July 2013 initial public offering in which we received net proceeds of $24.3 million, our March 2015 public offering in which we received net proceeds of $11.1 million, our March 2016 public offering in which we received net proceeds of $6.1 million, an additional $3.9 million from the exercise of 386,343 warrants, our March 2017 public offering in which we received net proceeds of approximately $4.1 million, our November 2017 public offering in which we received net proceeds of approximately $2.4 million, our May 2018 public offering in which we received net proceeds of approximately $18.8 million and an additional $4.8 million from the exercise of warrants, and our November 2018 public offering in which we received net proceeds of approximately $12.7 million. In addition, we received $7.5 million from our debt facility, which has subsequently been paid back in full as of December 31, 2016 and have received an aggregate of $9.3 million of net proceeds from sales of shares of our common stock through the At Market Issuance Sales Agreement (the "FBR Sales Agreement") with FBR Capital Markets & Co. through December 31, 2018. As of December 31, 2019, we have received $13.7 million in grant funding from the CPRIT Grant through Pelican. On January 18, 2018, we entered into the H.C. Wainwright Sales Agreement which replaced the FBR Sales Agreement and which has been subsequently terminated. To date, we received net proceeds of approximately $3.8 million from the sale of shares of our common stock through the H.C. Wainwright Sales Agreement. On January 21, 2020, we closed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $6.4 million. Subsequent to the year ended December 31, 2019, we have issued an additional 12,051,735 shares of common stock in "at-the-market" offerings and received $10.8 million of net proceeds. Cash and cash equivalents at March 23, 2019 were approximately $25.6 million. As of December 31, 2019, we had an accumulated deficit of $104.6 million. We had net losses of $20.4 million and $16.6 million for the years ended December 31, 2019 and 2018, respectively.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates and as we continue to fund the Pelican matching funds required in order to access the CPRIT Grant. 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. Although we currently have sufficient funds to complete our Phase 2 clinical trials, as currently planned, and expect that we will have sufficient funds to fund our operations through year end 2020, we will need to obtain substantial additional future funding in connection with our future planned clinical trials. 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. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

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

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

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

- Revenue;
- Deferred revenue;
- In-process R&D;
- Goodwill impairment;
- Income tax;
- Contingent consideration;
- Stock-based compensation;
- Research and development costs, including clinical and regulatory cost; and
- Recent accounting pronouncements.

Revenue

Our 2019 and 2018 revenue consisted of research funding from our CPRIT Grant. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred revenue until the services are performed and the conditions of the award are met.

Deferred Revenue

Deferred revenue is comprised of proceeds of \$3.4 million received from CPRIT for which the costs have not been incurred or the conditions of the award have not been met and grant funds received from an economic development grant agreement with the City of San Antonio ("Economic Development Grant") that we entered into on November 1, 2017. Under the Economic Development Grant, we received \$0.2 million in state enterprise fund grants for the purpose of defraying costs toward the purchase of laboratory equipment. As part of the agreement, we will provide the city of San Antonio with a purchase money security interest in the equipment to secure the repayment of grant funds should we fail to perform under the terms and conditions of the agreement. Our obligations under the agreement include meeting certain employment levels for a period of not less than seven years commencing on or before December 31, 2017 and establishing Pelican's corporate headquarters in San Antonio. The Economic Development Grant funds will be recognized as income upon the achievement of the performance criteria and determination that the cash is no longer refundable to the State of Texas.

In-process R&D

In-process research and development ("IPR&D") assets represent the fair value assigned to technologies that were acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval, and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. The IPR&D assets were acquired on April 28, 2017 when we acquired Pelican.

Goodwill and Impairment

Goodwill is tested for impairment annually or more frequently if changes in circumstances or the occurrence of events suggest that impairment may exist. We use widely accepted valuation techniques to determine the fair value of its reporting units used in its annual goodwill impairment analysis. Our valuation is primarily based on qualitative and quantitative assessments regarding the fair value of the reporting unit relative to its carrying value. See Note 7 regarding impairment at December 31, 2019.

Income Tax

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

In accordance with FASB ASC 740, Accounting for Income Taxes, we reflect in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2019 and 2018, we had no unrecognized income tax benefits and correspondingly there is no impact on our effective income tax rate associated with these items. Our policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2019 and 2018, we had no such accruals.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. The fair value of restricted stock units is estimated based on the closing price of our stock on the date of grant, and for the purposes of expense recognition, the total new number of shares expected to vest is adjusted for estimated forfeitures. We apply the Black-Scholes-Merton option pricing model to determine the fair value of our stock options awards. Inherent in this model are assumptions related to expected stock-price volatility, expected option life, risk-free interest rate and dividend yield. We do not have sufficient history to estimate the volatility of our common stock, therefore we have elected to utilize a peer group of similar publicly traded companies for which the historical information is available. We estimate the expected life of our options using the simplified method. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate to remain at zero. We account for forfeitures as they occur. 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.

Research and Development Costs

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

Recent Accounting Pronouncements

In November 2018, the FASB issued ASU 2018-18: *Collaborative Arrangements (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606. This ASU, in part, requires that certain transactions with collaboration partners be excluded from revenue recognized under Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company adopted this ASU in the first quarter of 2020 and there was no material effect on the recognition or measurement of revenue in the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of Topic 606. The Company adopted this ASU in the first quarter of 2019 and there was no material effect on the Company's results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-08, *Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*, which is intended to clarify and improve the scope and the accounting guidance for contributions received and contributions made. The amendments in ASU No. 2018-08 should assist entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transaction) within the scope of Topic 958, Not-for-Profit Entities, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. This amendment applies to all entities that make or receive grants or contributions. This ASU is effective for public companies serving as a resource recipient for fiscal years beginning after June 15, 2018, including interim periods within that fiscal year. The Company adopted this ASU in the first quarter of 2019 and there was no material effect on the recognition or measurement of revenue in the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires recognition of a right-of-use asset and liability for future lease payments for contracts that meet the definition of a lease and requires disclosure of certain information about leasing arrangements. Generally, a lease exists when a contract or part of a contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In determining whether a lease exists, the Company considers whether a contract provides it with both the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the identified asset. The Company adopted the standard on January 1, 2019 using the optional transition method and, as a result, did not recast prior period unaudited comparative financial statements. The Company has determined that its leases, consisting of leases for office and laboratory space without optional terms or variable components, are operating leases. Adoption of the new standard resulted in the recording of operating lease right-of-use assets and associated lease liabilities of $520,399 and $528,253, respectively, as of January 1, 2019 on the consolidated balance sheet with no cumulative impact to accumulated deficit and did not have a material impact on our results of operations or cash flows.

RESULTS OF OPERATIONS

Year Ended December 31, 2019 and 2018

Revenues

The CPRIT Grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT. Consequently, Pelican is required to raise $7.6 million in matching funds over the four year project.

As of December 31, 2019, CPRIT has provided $13.7 million of the total $15.2 million grant. The remaining $1.5 will become available upon project close, rather than in advance of expending the funds as in prior grant years. As of December 31, 2019, we have provided approximately $5.2 million which was used to satisfy Pelican's matching fund obligation under the first three years of the CPRIT Grant and we have approximately $2.4 million remaining to provide for the fourth CPRIT fiscal year.

Upon commercialization of the product, the terms of the Grant Contract require Pelican to pay tiered royalties in the low to mid-single digit percentages. Such royalties reduce to less than one percent after a mid-single-digit multiple of the grant funds have been paid to CPRIT in royalties.

We recognized grant revenue of approximately $3.0 million for the year ended December 31, 2019 for qualified expenditures under the grant. We recognized $5.8 million grant revenue related to CPRIT during the year ended December 31, 2018. As of December 31, 2019, we had short-term deferred revenue of $3.4 million for proceeds received but for which the costs had not been incurred or the conditions of the award had not been met.

Operating Expenses

Total operating expenses for the years ended December 31, 2019 and 2018, were $23.8 million. For the year ended December 31, 2019 operating expenses are primarily comprised of research and development, general and administrative expenses, goodwill impairment loss, and a change in the fair value of contingent consideration due to our initial acquisition of an 80% controlling interest in Pelican in 2017. Research and development expenses were $13.0 million, general and administrative expenses were $9.5 million, goodwill impairment loss was $0.7 million and the change in fair value of contingent consideration was $0.6 million for the year ended December 31, 2019 as compared to research and development expenses of $16.2 million, general and administrative expenses were $7.0 million and the change in fair value of contingent consideration was $0.5 million for the year ended December 31, 2018. For the year ended December 31, 2019, research and development expenses represented approximately 55% of operating expenses, general and administrative expenses represented approximately 39%, goodwill impairment represented approximately 3% and change in fair value of contingent consideration 3% of operating expenses. For the year ended December 31, 2018, research and development expenses represented approximately 68% of operating expenses, general and administrative expenses represented approximately 30% and change in fair value of contingent consideration 2% of operating expenses.

Research and development expense

Research and development expenses decreased by 20% to $13.0 million for the year ended December 31, 2019 compared to $16.2 million for the year ended December 31, 2018. The components of R&D expense are as follows, in millions:

	Year ended December 31,	
	2019	2018
Programs		
HS-110	$ 0.1	$ 3.5
HS-410	—	0.2
HS-130	0.4	0.8
PTX 35/other biologics against TNFRSF25	3.0	7.5
Other programs	3.3	0.4
Unallocated research and development expenses	6.2	3.8
	$ 13.0	$ 16.2

- HS-110 expense decreased $3.4 million, as patient enrollment was completed for the phase 2 portion of our multi-arm clinical trial.
- HS-410 expense decreased $0.2 million due to completion of long-term follow up and program close-out.
- HS -130 expense decreased by $0.4 million as we continue CMC (chemistry, manufacturing and control) development, and prepare for production of clinical trial material for this program.
- PTX expense for the year ended December 31, 2019 was $3.0 million as manufacturing costs were higher in 2018.
- Other programs include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies. These costs increased by approximately $2.9 million related to the variability and timing of collaborative programs focused on T-cell costimulatory programs including the Zika program.
- Unallocated expenses include personnel-related expenses, professional and consulting fees, and travel and other costs. These costs increased approximately $2.4 million primarily related to stock compensation expense and employee salary expense.

General and administrative expense

General and administrative expense increased approximately 36% to $9.5 million for the year ended December 31, 2019 compared to $7.0 million for the year ended December 31, 2018. The variance of $2.5 million is primarily due to the increase in personnel and stock compensation expense.

Change in fair value of contingent consideration

We reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The change in the fair value of contingent consideration was $0.6 million for the year ended December 31, 2019 compared to the change in fair value of contingent consideration of $0.5 million for the year ended December 31, 2018.

Goodwill impairment loss

During the year ended December 31, 2019, the Company experienced a sustained decline in the quoted market price of the Company's common stock and as a result the Company determined that it was more likely than not that the carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, the Company performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. As a result, the Company recorded an impairment loss of $0.7 million on the goodwill during the year ended December 31, 2019.

Interest income

Interest income was $0.4 million for the year ended December 31, 2019 compared to $0.3 million for the year ended December 31, 2018. The increase is due to the investment in various short-term financial instruments that generated interest income during the year ended December 31, 2019.

Income tax expense

Income tax expense for the year ended December 31, 2019 was $0.04 million. Income tax benefit for the year ended December 31, 2018 consists of $1.0 million federal tax benefit due to the application of the tax benefit calculated on the indefinite-lived 2018 NOLs.

Net loss attributable to Heat Biologics, Inc.

We had a net loss attributable to Heat Biologics, Inc. of $20.0 million, or ($0.60) per basic and diluted share for the year ended December 31, 2019 compared to a net loss attributable to Heat Biologics, Inc. of $15.7 million, or ($0.90) per basic and diluted share for the year ended December 31, 2018.

BALANCE SHEET AS OF DECEMBER 31, 2019 AND 2018

Short-term Investments. Short-term investments were $5.7 million as of December 31, 2019 compared to $5.6 million as of December 31, 2018. The Company invested cash in higher yield investments to generate interest income.

Prepaid Expenses and Other Current Assets. Prepaid expenses and other current assets was approximately $0.4 million as of December 31, 2019 and $1.0 million as of December 31, 2018. The $0.6 million decrease was primarily attributable to the amount recognized for cGMP as we continue our manufacture of PTX-35 antibody.

In-Process R&D. As of December 31, 2019 and December 31, 2018, we had in-process R&D of $5.9 million from our acquisition of Pelican. The carrying value of this asset did not change during the year ended December 31, 2019.

Goodwill. As of December 31, 2019 and December 31, 2018, we had goodwill of $1.5 million and $2.2 million, respectively, from our acquisition of Pelican. The fair value of this asset decreased by $0.7 million due to a goodwill impairment charge for the excess of the reporting unit’s carrying value over its fair value in 2019.

Operating and finance lease right-of-use assets. The increase is due to the adoption of ASC 842.

Accounts Payable. Accounts payable was approximately $1.5 million and $1.0 million as of December 31, 2019 and December 31, 2018. The $0.5 million increase was primarily due to payables for CMC as well as investigator site payments for our clinical trials.

Deferred Revenue. We had short term deferred revenue of $3.4 million and $1.0 million as of December 31, 2019 and December 31, 2018, respectively. This short term deferred revenue represents proceeds received for the CPRIT grant but for which the costs had not been incurred or the conditions of the award had not been met. We had long term deferred revenue of $0.2 million as of December 31, 2019 and 2018, related to an economic development grant received from San Antonio for the purchase of lab equipment.

Accrued Expenses and Other Liabilities. Accrued expenses were approximately $1.7 million as of December 31, 2019 which was consistent with the balance at December 31, 2018 of approximately $1.7 million.

Operating and financing lease liabilities. Current and long term liabilities related to operating and finance leases was $1.9 million as of December 31, 2019. These balances are related to our office lease and equipment leases.

Deferred Tax Liability. Deferred tax liability was approximately $0.4 million as of December 31, 2019 compared to approximately $0.3 million as of December 31, 2018.

Contingent Consideration. As of December 31, 2019, we had contingent consideration of $3.7 million compared to $3.1 million for the year ended December 31, 2018 related to our acquisition of Pelican which is recorded on our consolidated balance sheets. This amount represents the fair value of future milestone payments to Pelican shareholders which were discounted in accordance with ASC 805. We perform an analysis on a quarterly basis and for the year ended December 31, 2019, we determined the change in the estimated fair value of the contingent consideration to be approximately $0.6 million due to the effect of the change in discount rate, probability of achieving milestones, and passage of time on the fair value measurement.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

Since our inception in June 2008, we have incurred significant losses and we have financed our operations with net proceeds from the private placement of our preferred stock, common stock and debt. More recently, we have primarily financed our operations with net proceeds from the public offering of our common stock and to a lesser extent, the proceeds from the exercise of warrants. During May 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $18.8 million and after the closing of the offering, an additional $4.8 million from the exercise of 3,054,667 warrants issued in this offering. During November 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $12.7 million. In addition, from August 2016 through July 2017 we received an aggregate of $9.3 million of net proceeds through our At Market Issuance Sales Agreement (the "FBR Sales Agreement") with B. Riley FBR, Inc. formerly known as FBR Capital Markets & Co. On January 18, 2018, we entered into the H.C. Wainwright Sales Agreement that replaced the FBR Sales Agreement and which has subsequently been terminated. We received net proceeds of approximately $3.8 million from the sale of shares of our common stock through the H.C. Wainwright Sales Agreement. On January 21, 2020, we closed an underwriters public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $6.4 million. Subsequent to the year ended December 31, 2019, we have issued an additional 12,051,735 shares of common stock in "at-the-market" offerings and received $10.8 million of net proceeds. As of December 31, 2019, we had an accumulated deficit of approximately $104.6 million. We had net losses of $20.4 million and $16.6 million for the years ended December 31, 2019 and 2018, respectively.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development and advance our clinical trials of, and seek marketing approval for, our product candidates and as we continue to fund the Pelican matching funds required in order to access the CPRIT Grant. 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. Although we currently have sufficient funds to complete our Phase 2 clinical trials, as currently planned, and expect that we will have sufficient funds to fund our operations through year end 2020, we will need to obtain substantial additional future funding in connection with our future planned clinical trials. 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. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to focus our resources on our product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so. As of December 31, 2019, we had approximately $14.8 million in cash and cash equivalents and short-term investments.

Cash Flows

Operating activities. The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The significant decrease in cash used in operating activities for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily due to advanced funding received from CPRIT relating to the fourth year of the grant , a reduction in prepaid manufacturing costs and timing of payments to vendors for primarily clinical trial expenses.

Investing activities. Cash used by investing activities during the year 2019 was related to purchase of property and equipment for our lab and new office space. Cash used by investing activities during the year 2018 was related to purchase of short-term investments and the purchase of lab equipment as we established our San Antonio facilities as required per the CPRIT Grant.

Financing activities. Cash provided by financing activities during the year ended December 31, 2019 decreased significantly from 2018 as there were no public offerings in 2019. Cash provided by financing activities during the year ended December 31, 2018 was primarily from the May 7, 2018 public offering which generated net proceeds of approximately $18.8 million and an additional $4.8 million from the exercise of warrants, the November 21, 2018 public offering which generated net proceeds of approximately $12.7 million, as well as approximately $3.8 million net proceeds from the HCW sales agreement.

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 $104.6 million through December 31, 2019. We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

We intend to meet our financing needs throughmultiple alternatives, including, but not limited to, additional equity financings, debt financings and/or funding from partnerships or collaborations.

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

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;

- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals; and
- profitability of our clinical laboratory diagnostic and microbiology services business.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan, including accessing the CPRIT Grant. 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 Obligations

Our contractual obligations as of December 31, 2019 are as follows (in thousands):

	2020	2021	2022	2023	2024	Thereafter	Total
License agreements (1)	$ 103	$ 228	$ 784	$ 74	$ —	$ —	$ 1,189
Operating lease obligations (2)	321	330	339	245	232	693	2,160
Finance lease obligations (2)	59	59	94	—	—	—	212
Total	$ 483	$ 617	$ 1,217	$ 319	$ 232	$ 693	$ 3,561

(1) License agreements for each year are associated with the University of Miami and in 2020 an additional $25,000 for the University of Michigan cell line agreement.
(2) See Note 13 to our consolidated financial statements in for additional information regarding leases.

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-32.

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

None.

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

Disclosure Controls and Procedures

Our management has adopted and maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Principal Executive Officer and Principal Financial Officer has conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Our internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of our internal control over financial reporting based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework* (2013). Based on the assessment, management concluded that, as of December 31, 2019, our internal controls over financial reporting were effective at the reasonable assurance level based on those criteria.

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

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.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our last quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

None.

PART III

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

Below is certain information regarding our directors and executive officers.

Name	Age	Position	Served as an Officer or Director Since
Jeffrey Wolf	56	Chairman of the Board of Directors, Chief Executive Officer and President	2008
Jeff T. Hutchins, Ph.D.	61	Chief Scientific Officer and Chief Operating Officer	2017
William L. Ostrander	52	Vice President of Finance and Secretary	2019
John Monahan, Ph.D.	73	Director	2009
John K.A. Prendergast, Ph.D.	66	Director	2016
Edward B. Smith, III	44	Director	2010

Jeffrey Wolf, ***Chairman of the Board of Directors, Chief Executive Officer and President***

Mr. Wolf has served our Chairman of the Board of Directors, Chief Executive Officer and President since our inception. He founded Heat Biologics in August 2008. Mr. Wolf served from June 1997 to March 2011, as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several biomedical companies. Mr. Wolf's start-ups include Avigen, a gene therapy company where he was a co-founder and director; TyRx Pharma, a company focused on the development of bio-compatible polymers where he was a co-founder and Chairman; and 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. 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 clinical stage company developing therapeutics to protect the gut microbiome.

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

Jeff T. Hutchins, Ph.D., ***Chief Scientific Officer and Chief Operating Officer***

Dr. Hutchins joined our company on January 1, 2017 as Chief Scientific Officer and Senior Vice President of Pre-Clinical Development and in June 2017 he was appointed as both Chief Scientific Officer and Chief Operating Officer. Dr. Hutchins oversees our research efforts, bringing over 27 years of research and clinical development experience from both large pharmaceutical and biotechnology companies. Most recently and since 2012, Dr. Hutchins served as Vice

President of Preclinical Research for Peregrine Pharmaceuticals, Inc., a biopharmaceutical company developing therapeutics to fight cancer and infectious diseases. Dr. Hutchins was responsible for building out the research program for Peregrine's lead product candidate, bavituximab, a chimeric monoclonal antibody designed to target phosphatidylserine. Prior to joining Peregrine in 2012, from 2001 until 2012, Dr. Hutchins served as Vice President, Preclinical Development at Inhibitex Inc, which was acquired by Bristol-Myers Squibb. From 1991 to 2000, Dr. Hutchins held several senior scientist positions in Discovery Research at Burroughs Wellcome and Glaxo Wellcome, with a visiting professor appointment at Rush Medical College.

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

William Ostrander*, Vice President of Finance, and Secretary*

Mr. Ostrander joined our Company as Vice President of Finance and Secretary in September 2019. Mr. Ostrander has over 22 years of experience in financial management at public and private companies. Before joining Heat Biologics, Bill served as Executive Director of Finance at Liquidia Technologies, a publicly-traded biopharmaceutical company. Prior to that, he served as Senior Director of Finance and Accounting at KBI Biopharma, a biopharmaceutical contract services company. He also served as Manager of Finance at LexisNexis Risk Solutions, a data analytics solutions company. Prior to that, he served as Controller of Seisint Inc., a private information products company that was acquired by LexisNexis. He also served as Senior Manager, Finance and held other accounting and finance positions for Boca Research, a data communications hardware manufacturer. Mr. Ostrander holds a B.S. in Finance from Central Michigan University.

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

Dr. Monahan has served on our Board since November 2009 and is currently a consultant to Synthetic Biologics, Inc., a clinical stage company developing therapeutics to protect the gut microbiome (NYSE MKT: SYN). Dr. Monahan Co-Founded Avigen Inc. (Nasdaq: AVGN) in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products for the treatment of serious human diseases. Over a 12 year period as CEO of Avigen he raised over $235M in several private and public financings including its IPO. From 1989-1992, he was VP of R&D at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an Instructor at Baylor College of Medicine, Houston TX. He received his Ph.D. in Biochemistry in 1974 from McMaster University, Canada and his B.Sc. from University College Dublin, Ireland in 1969. Dr. Monahan is a Scientific Advisory Board member of Agilis Biotherapeutics. He is also a board member of the biotech company ITUS Corporation and also a board member of a number of Irish biotech companies including Genable, Cellix, Luxcel, and GK Technologies.

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

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

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

Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

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

Edward B. Smith, III, *Director*
Mr. Smith has served on our Board since November 2010. Since January 1, 2015, Mr. Smith has also been Managing Member of Aristar Capital Management, LLC, a New York-based investment firm founded in 2015. From April 14, 2017 through July 14, 2017, Mr. Smith served as the interim Chief Executive Officer and interim Chief Financial Officer Agritech Worldwide, Inc. ("Agritech," formerly Z Trim Holdings, Inc.) (OTCPink: FBER), a manufacturer of environmentally friendly agricultural functional ingredients, From January 2015 until May 2016, Mr. Smith also served as the Chief Executive Officer of Agritech and from 2009 through July 2017 he served as a board member of Agritech. From April 2005 through December 2014, Mr. Smith served as the Managing Partner of Brightline Capital Management, LLC ("BCM"), a New York-based investment firm founded in 2005. Prior to founding BCM, Mr. Smith worked at Gracie Capital from 2004-2005, GTCR Golder Rauner from 1999-2001 and Credit Suisse First Boston from 1997-1999. Mr. Smith holds a Bachelor of Arts in Social Studies from Harvard College and a Masters in Business Administration from Harvard Business School.

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

Committees of the Board of Directors

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

Board Members	Audit Committee	Compensation Committee	Nominating and Governance Committee
Jeffrey Wolf	—	—	—
John Monahan, Ph.D.	Member	Chairman	Member
Edward B. Smith, III	Chairman	Member	Chairman
John K.A. Prendergast, Ph.D.*	Member	Member	Member

* Dr. Prendergast serves as our independent Lead Director.

Audit Committee

Our common stock is listed on the Nasdaq Capital Market. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors and all members of our audit, compensation and nominating and governance committees must be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the Nasdaq Stock Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

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

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

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

Compensation Committee

Our Compensation Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast, each of whom is deemed to be independent in accordance with the Nasdaq definition of independence. Compensation Committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. This Committee determines, approves, and reports to the Board of Directors on all elements of compensation of our executive officers. The Compensation Committee also has the power to prescribe, amend, and rescind rules relating to our stock incentive plans, to recommend the grant of options and other awards under the stock incentive plans, and to interpret the stock incentive plans.

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

Our Compensation Committee annually reviews the compensation program for our Chief Executive Officer and other members of senior management and then makes recommendations to the full board for determination. In each case, the Committee takes into account the results achieved by the executive, his or her future potential, and his or her scope of responsibilities and experience. During our fiscal year ended December 31, 2019, the Committee evaluated the performance of our executives and considered the compensation levels and equity programs at comparable companies and related industries and the analysis of its outside consultant before it made its compensation recommendations to the full board, including recommendations regarding salary increases, awards of cash bonuses and awards of stock options.

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

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

Nominating and Governance Committee

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

The functions performed by the Nominating and Governance Committee include:

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

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

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

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

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

Board Leadership Structure

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

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

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

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

Risk Oversight

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

Delinquent Section 16(a) Reports

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 Forms 5 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, 2019.

Code of Business Conduct and Ethics

We have long maintained a Code of Business Conduct and Ethics that is applicable to all of our directors, officers and employees. 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. The code is posted on our website at www.heatbio.com.

Item 11. ***Executive Compensation***

We are a "smaller reporting company" and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about its executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2019 executive compensation program for our named executive officers.

Set forth below is the compensation paid or accrued to our Named Executive Officers during the years ended December 31, 2019 and December 31, 2018:

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (12)	Options (12)	Other	Total
Jeffrey Wolf	2019	$ 427,579	$ 213,789 (1)	$ 1,289,000	$ 615,200	$ 166,864 (2)	$2,712,432
Chairman and Chief Executive Officer	2018	$ 417,150	$ 417,150 (3)	$ 160,785	$ 171,533	$ —	$1,166,618
Jeff T. Hutchins	2019	$ 343,375	$ 103,013	$ 151,728	$ 274,425	$ —	$ 872,541
Chief Scientific Officer and Chief Operating officer	2018	$ 335,000	$ 201,000 (4)	$ —	$ 85,386	$ —	$ 621,386
William L. Ostrander	2019	$ 58,385 (5)	$ 11,677 (6)	$ —	$ 29,528	$ —	$ 99,590
Vice President of Finance (5)	2018	$ —	$ —	$ —	$ —	$ —	$ —
Robert Jakobs	2019	$ 121,517 (7)	$ —	$ —	$ —	$ 21,151 (8)	$ 142,668
Former Vice President of Finance (7)	2018	$ —	$ —	$ —	$ —	$ —	$ —
Ann A. Rosar	2019	$ 99,083 (9)	$ —	$ 47,398 (10)	$ 85,028	$ —	$ 231,509
Former Vice President of Finance (9)	2018	$ 260,000	$ 135,000 (11)	$ 17,865	$ 19,060	$ —	$ 431,925

(1) Mr. Wolf's annual 2019 bonus of $213,789 was accrued in 2019 and paid in 2020.
(2) This is a special bonus to cover the estimated taxes from the 900,000 restricted share award granted on 12/30/19.
(3) Mr. Wolf's annual 2018 bonus of $208,575 was paid in 2018. The one-time supplemental cash bonus of $208,575 was accrued in 2018 and paid in 2019.
(4) Dr. Hutchins' annual 2018 bonus of $100,500 was paid in 2018. The one-time supplemental cash bonus of $100,500 was accrued in 2018 and paid in 2019.
(5) Mr. Ostrander was appointed as our Vice President of Finance on September 25, 2019.
(6) Mr. Ostrander's annual prorated 2019 bonus of $11,677 was paid in 2019.
(7) Mr. Jakobs last day of employment was September 20, 2019.
(8) Mr. Jakobs was paid $18,333 for severance related to his separation agreement and $2,818 for accrued vacation.
(9) Ms. Rosar resigned as our Vice President of Finance on March 31, 2019 and her last day of employment was April 30, 2019. Regular pay of $88,833 plus $10,250 for accrued vacation was paid out for this period.
(10) Represents the value of the restricted stock award, net of forfeiture related to the last day of employment, April 30, 2019.
(11) Ms. Rosar's annual 2018 bonus of $65,000 was paid in 2018. Ms. Rosar received a performance bonus of $5,000 in June 2018. The one-time supplemental cash bonus of $65,000 was accrued in 2018 and paid in 2019.
(12) For all stock options and stock awards, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC 718. Assumptions made in the calculation of these amounts are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2018 and 2019.

Narrative Disclosure To Summary Compensation Table

Overview of Our Compensation Program

A. Philosophy and Objectives

Our primary objective with respect to executive compensation is to design compensation programs that will align executives' compensation with our overall business strategies for the creation of stockholder value and attract, motivate and retain highly qualified executives.

Our executive compensation program is based on the following philosophies and objectives:

- *Compensation Should Align with Stockholders' Interests* — The Compensation Committee and our Board believes that executives' interests should be aligned with those of the stockholders. Executives are granted restricted stock and stock options so that their total compensation is tied directly to the value realized by our stockholders. Executive bonuses are tied directly to company strategy and operational execution which contributed to our success as a whole.

- *Compensation is Competitive* — The Compensation Committee and Board seek to provide a total compensation package that attracts, motivates and retains the executive talent that we need in order to maximize the return to stockholders and execute our operational and scientific strategy. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable in relation to comparable companies with which we compete for talent.

- *Compensation Motivates and Rewards the Achievement of Goals* —Our executive compensation program is designed to appropriately reward both individual and collective performance that meets and exceeds our annual and long-term strategic and operational goals. To accomplish this objective, a substantial percentage of total compensation is variable, "at risk", both through annual incentive compensation and the granting of long-term incentive awards.

We seek to achieve these objectives through three key compensation elements:

- a base salary;

- a performance-based annual cash incentive (i.e., annual cash incentive compensation); and

- long term equity awards.

In order to enhance the Compensation Committee's ability to carry out its responsibilities effectively, as well as maintain strong links between executive pay and performance, the Compensation Committee reviews compensation information for each Named Executive Officer, which includes the following information:

- the annual compensation and benefit values that are being offered to each executive;

- the value of all outstanding equity awards; and

- discussions with our Chairman, Chief Executive Officer and other senior management in connection with compensation matters, as well as compensation consultants and other advisors from time to time.

B. Compensation Administration

Roles and Responsibilities of Compensation Committee

The primary purpose of the Compensation Committee is to conduct reviews of our general executive compensation policies and strategies and oversee and evaluate our overall compensation structure and programs. The Compensation Committee seeks to confirm that total compensation paid to our Named Executive Officers during the year ended December 31, 2019, was reasonable and competitive. Our Named Executive Officers for the year ended December 31, 2019 were as follows Jeffrey Wolf, our Chief Executive Officer, William Ostrander, our Vice President of Finance, Jeff Hutchins, our Chief Scientific Officer and Chief Operating Officer and Ann Rosar and Robert Jakobs, each our Former Vice Presidents of Finance (collectively, our "Named Executive Officers"). Responsibilities of the Compensation Committee include, but are not limited to:

- Establishing on an annual basis performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers, evaluating the performance of such officers in light of those goals and objectives, and setting the compensation level for those officers based on this evaluation.

- Recommending to the Board the compensation for independent Board members (including retainer, committee and committee chair's fees, stock options and components of compensation as appropriate).

- Reviewing the competitive position of, and making recommendations to the Board with respect to, the cash-based and equity-based compensation plans and other programs relating to compensation and benefits.

- Reviewing our financial performance and operations as well as our major benefit plans.

- Overseeing the administration of our stock option and other executive compensation plans, including recommending to the Board of Directors the granting of options and awards under the plans, and the approval or disapproval of the participation of individual employees in those plans.

- Reviewing and approving for our Chief Executive Officer and other senior executive officers: (a) employment agreements; (b) severance agreements; (c) change in control agreements/provisions; and (d) any other material perquisites or other in-kind benefits.

Additional information regarding the Compensation Committee's responsibilities is set forth in its charter, which is posted on our website at *www.heatbio.com*.

Use of Compensation Consultant

The Compensation Committee retained Korn Ferry, a nationally-recognized global human resources consulting firm, as its independent compensation advisor for 2018 and 2019. Korn Ferry principally provides analysis, advice and recommendations regarding named executive officer and non-employee director compensation as well as guidance and considerations on our long-term incentive program for all eligible employees including salary, bonus, benefits and equity awards for our executive officers and retainers, meeting fees and equity awards for our directors. Korn Ferry reports to the Chairman of the Compensation Committee and has direct access to the other members of the Compensation Committee. Korn Ferry does not provide any other services to the Company other than in its role as the Compensation Committee's independent advisor. The Compensation Committee has evaluated Korn Ferry's reports and, as they considered appropriate to achieve the best interests of the Company and its stockholders, implemented the recommendations.

The Compensation Committee considered whether Korn Ferry had any conflicts of interest in advising the Committee. In doing so, the Compensation Committee considered whether Korn Ferry had been providing services of any other nature to us; the amount of fees received from us by Korn Ferry; the policies and procedures adopted by Korn Ferry that have been designed to prevent conflicts of interest; whether any business or personal relationships existed between the consultants employed by Korn Ferry who worked on our matters and any member of the Compensation Committee; whether any business or personal relationship existed between such consultants and any of the our executive officers; and whether Korn Ferry or such consultants hold any of our common stock. Upon evaluating such considerations, the Committee found no conflicts of interest in Korn Ferry advising the Compensation Committee.

Role of the Chief Executive Officer

Our Chief Executive Officer, Mr. Wolf, makes recommendations to the Compensation Committee regarding the compensation of our other named executive officers. Mr. Wolf does not participate in any discussions or processes concerning his own compensation and participates in a non-voting capacity in discussions or processes concerning the compensation of our Principal Financial Officer and other members of management.

Compensation Committee Consideration of Shareholder Advisory Votes

At our annual meeting of stockholders held on July 23, 2019, we submitted the compensation of our Named Executive Officers to our stockholders in a nonbinding vote. Our executive compensation program received the support of holders of approximately 84% of the shares that voted on this proposal at the meeting (including abstentions but excluding broker non-votes). At our annual meeting of stockholders held on July 23, 2019, our stockholders voted on an advisory basis with respect to the frequency of future advisory votes on executive compensation. Holders of a majority of the shares that voted on this proposal at the meeting (including abstentions but excluding broker non-votes) expressed their preference for an advisory vote every three years. Accordingly, we intend to hold an annual advisory vote on executive compensation at our annual meeting of stockholders in 2022.

C. Competitive Considerations

In making compensation decisions with respect to each element of compensation for our Named Executive Officers, the Compensation Committee believes that it is important to be informed as to the competitive market practices at similarly-situated public companies. In setting 2019 and 2020 target total direct compensation levels for our Named Executive Officers, the Compensation Committee relied in part on reports prepared by Korn Ferry in December 2018 and December 2019, respectively. In December 2019, Korn Ferry conducted a comprehensive assessment of our named executive officer pay program relative to a premier compensation survey which is specific to our size and industry and a peer group of 18 similarly-situated public companies focused on oncology at a similar clinical development stage, which included the following compensation elements: (1) base salary, (2) target annual incentives (bonuses), (3) target total cash compensation, (4) long-term incentives and (5) target total direct compensation. In addition, Korn Ferry also provided an analysis of our pay mix and long-term incentive program relative to peer group practices. Korn Ferry's assessment included our Chief Executive Officer, our Vice President of Finance and our Chief Operating Officer/ Chief Scientific Officer. The Compensation Committee considered the competitive market pay data from both our publicly-traded peer group that was included in Korn Ferry's analysis and relevant survey data which is specific to our size and industry. In December 2018, Korn Ferry also conducted a comprehensive assessment of our named executive officer pay program relative to a premier compensation survey which is specific to our size and industry and market data from 14 similarly-situated biotechnology, pharmaceuticals and biopharma companies.

The Compensation Committee's desired competitive positioning and its pay program decision-making (in terms of both compensation levels and overall mix of pay which is focused on variable or "at risk" compensation) is reflective of our pay for performance philosophy and provides alignment of executive and shareholder interests.

We believe that, given the industry in which we operate and our compensation philosophy and objectives, our approach to executive compensation is sufficient to retain our current executive officers and to hire new executive officers when and as required.

D. Components of Compensation

The allocation between cash and non-cash named executive officer compensation is influenced by subjective and objective factors considered by the Compensation Committee and is intended to reflect the Compensation Committee's determination of the appropriate compensation mix among base pay, annual cash incentives and long-term equity incentives for each named executive officers.

1. Base Salaries

We provide our Named Executive Officers a base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers the scope and accountability associated with each Named Executive Officer's position and such factors as performance and experience of each Named Executive Officer. We design base pay to provide the essential reward for an employee's work and are required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay may be provided to recognize an employee's specific performance achievements. The base salaries are targeted to be competitive with other similar biotechnology companies. Base salaries for the Named Executive Officers are set by their respective employment contracts and are reviewed annually by the Compensation Committee. Our Chief Executive Officer, Vice President of Finance and Chief Scientific Officer/ Chief Operating Officer typically make performance assessments of our other employees throughout the year, and provide ongoing feedback to employees, provide resources and maximize individual and team performance levels. Based on the analysis provided to us by Korn Ferry and other comparative research performed by the Committee, the Committee was able to compare the base salary for the Chief Executive Officer, Vice President of Finance and Chief Scientific Officer/ Chief Operating Officer to those of the proxies of a peer group of 18 publicly traded companies competing within the same industry as the Company and at similar stages of clinical development and external survey published data. It was determined that our Chief Executive's Officer's, Vice President of Finance and Chief Scientific Officer's/ Chief Operating Officer's 2019 base salary levels were within a competitive range of market relative to competitive market data and therefore only modest merit-related base salary increases were provided for 2019 and cost of living adjustments of 3% of base salary were provided for 2020. The 2019 and 2020 base salaries for our current Named Executive Officers are as follows:

Named Executive Officer	Base Salary 2019	Base Salary 2020
Jeffrey Wolf, Chief Executive Officer	$ 427,579	$ 440,406
William L. Ostrander, Vice President of Finance	$ 220,000	$ 226,600
Jeff Hutchins, Chief Scientific Officer and Chief Operating Officer	$ 343,375	$ 353,676

2. Bonuses

The Compensation Committee also makes recommendations to the full Board of Directors for determining bonuses. For the year ended December 31, 2019, the Compensation Committee awarded a $213,789 cash bonus for Jeffrey Wolf (50% of gross base salary), a $103,013 cash bonus for Jeff T. Hutchins, Ph.D. (30% of gross base salary) and a $11,677 cash bonus for William Ostrander (20% of gross base salary, pro-rated from the date of his employment commencement on September 25, 2019.

On December 31, 2019, Mr. Wolf was also paid a gross up cash payment of $166,864 to cover the estimated taxes with respect to his restricted stock award that he received in December 2019, which was in addition to his annual cash bonus for 2019. On January 2, 2020, Mr. Wolf was also paid a gross up cash payment of $367,100 to cover the estimated taxes with respect to the restricted stock award he received in January 2020.

For the year ended December 31, 2018, the Compensation Committee approved a $208,575 cash bonus for Jeffrey Wolf (50% of pro-rated gross base salary), a $100,500 cash bonus for Jeff T. Hutchins, Ph.D. (30% of pro-rated gross base salary) and a $65,000 cash bonus for Ann Rosar (25% of pro-rated gross base salary). In addition, on January 1, 2019, the Board of Directors granted the following one-time supplemental cash bonuses to the executive officers for significant strategic and operational achievements in 2018: (i) Mr. Wolf a one-time supplemental cash bonus equal to $208,575; (ii) Ms. Rosar a one-time cash supplemental bonus equal to $65,000 and (iii) Dr. Hutchins a one-time supplemental cash bonus equal to $100,500.

The employment agreement with Jeffrey Wolf that was in effect during 2018 and 2019 provided that he was eligible for a cash performance bonus of up to fifty percent (50%) of his base as well an equity bonus in the sole discretion of the board of directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the board of directors.

Dr. Hutchins employment agreement was amended in January 2019 to increase his bonus such that he is eligible for a cash performance bonus of up to thirty percent (30%) of his base and as well an equity bonus in the sole discretion of the board of directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the board of directors. William Ostrander's offer letter provides for an annual bonus of up to twenty percent (20%) of his base and as well as an equity bonus in the sole discretion of the Board of Directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the board of directors. The Compensation Committee believes that the granting of a bonus is appropriate to motivate the Named Executive Officers. The Compensation Committee focuses on individual performance, which enables the Compensation Committee to differentiate among executives and emphasize the link between personal performance and compensation. Although the Compensation Committee does not use any fixed formula in determining bonuses, it does link them to financial objectives of importance to it.

3. Long-Term Incentives

The Compensation Committee believes that a substantial portion of the Named Executive Officer's compensation should be awarded in equity-based compensation since equity-based compensation is directly linked to the interests of stockholders. The rationale for making equity awards was to use the awards to encourage retention and better align the interest of the named executive officers with the stockholders. The Compensation Committee has elected to grant a combination of stock options and restricted stock awards to the Named Executive Officers and other key employees as the primary long-term incentive vehicles. In making this determination, the Compensation Committee considered a number of factors including: the accounting impact, potential value of restricted stock and stock option grants versus other equity instruments and cash incentives, and the alignment of equity participants with stockholders. In determining equity awards, the Compensation Committee focused on the pro forma percent ownership as compared to executive officers in similar companies.

In 2019 and 2020 the Board also considered each Named Executive Officer prior long term service and the fact that there was a lack of realizable value from their prior awards since substantially all of the prior awards were of significant low value and/or underwater. In addition, the Compensation Committee also sought to better align the Chief Executive Officer's equity ownership interest in our company with that of other chief executive officers of similarly situated public companies. The Compensation Committee determined in December 2019 and January 2020 to grant restricted stock awards to the Chief Executive Officer.

In December 2019, Jeffrey Wolf was granted 900,000 restricted stock awards as part of his long-term incentive compensation for the year ended December 31, 2019. In addition, Jeffrey Wolf was granted 1,980,000 restricted stock awards in January 2020. The restricted stock awards will vest 50% immediately, 30% on the one-year anniversary of the grant date, 10% on the two-year anniversary grant date, and the remaining 10% on the three-year anniversary grant date. The restricted stock agreements with respect to the foregoing issuances of restricted stock, among other things, prohibit transfers of the restricted stock prior to the two-year anniversary of the grant date other than by will, laws of descent and distribution and in the event of death. In addition, sales or transfers made after the two year anniversary of the grant date are subject to the right of the Company to buy back the stock at any time that the holder desires to sell the restricted stock at a price equal to the lower of the closing price per share and 32 times the closing price per share on the date of grant.

Due to the limited number of awards available for grant under the 2018 Plan, the Compensation Committee intends to grant option awards to employees, including Dr. Hutchins and Mr. Ostrander, upon receipt of stockholder approval of an increase in the number of awards available for grant under the 2018 Plan.

Each of Jeffrey Wolf, Jeff T. Hutchins, Ph.D. and Ann Rosar were granted options to purchase 800,000, 356,860 and 110,570 shares of common stock, respectively, in January 2019 as part of their annual long-term incentive compensation. In addition, Jeffrey Wolf, Jeff T. Hutchins, Ph.D. and Ann Rosar were issued 800,000, 143,140 and 89,430 restricted stock awards, respectively in January 2019, as part of their annual long-term incentive compensation. The stock options and restricted stock awards granted vest 50% immediately, 30% on the one-year anniversary of the grant date, 10% shall vest on the two-year anniversary grant date, and the remaining 10% shall vest on the three-year anniversary grant date. The stock options have a term of ten years. Mr. Ostrander was granted an option to purchase 75,000 shares of common stock on September 25, 2019, upon his commencement of employment, that vests pro rata over four years.

The Compensation Committee reviews the performance, potential burn rates and dilution levels to create an option pool that may be awarded to employee participants. Grants to the Named Executive Officers were determined by the Compensation Committee after reviewing market data, including the reports and analysis discussed above and after considering each executive's performance, role and responsibilities as well as consideration of specific issues related to voting of foreign shares.

The Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

Former Vice President of Finance Compensation.

Ann Rosar served as our Vice President of Finance/ Controller from April 2016 until March 31, 2019. Prior to her resignation, she was compensated in accordance with her employment agreement and other benefits consistent with those provided to members of management. The details of the agreements relating to Ms. Rosar's employment and her separation can be found under "Employment Agreements." Ms. Rosar's base salary for 2019 and 2018 was $266,500 and $260,000, respectively, and she was eligible for a discretionary performance bonus. Ms. Rosar did not receive a bonus for services performed for the year ended December 31, 2019 as she resigned in March 2019; however she did receive a $65,000 cash bonus performance for services performed during the year ended December 31, 2018, a $5,000 bonus in June 2018 plus a one-time supplemental cash bonus of $65,000 for services performed during the year ended December 31, 2018.

Robert Jakobs served as our Vice President of Finance/ Controller from April 1, 2019 until September 20, 2019. Prior to his resignation, he was compensated in accordance with his offer letter and other benefits consistent with those provided to members of management. The details of the agreement relating to Mr. Jakobs' employment and his separation can be found under "Employment Agreements." Mr. Jakobs base salary for 2019 was $220,000 and he was eligible for a discretionary performance bonus. Mr. Jakobs did not receive a bonus for services performed for the year ended December 31, 2019 as he resigned in September 2019.

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Outstanding Equity Awards at Fiscal Year-End (December 31, 2019)

	Option Awards				Stock Awards	
Name and Principal Position	**Number of securities underlying unexercised options/ exercisable**	**Number of securities underlying unexercised options/ unexercisable**	**Option exercise price**	**Option expiration date**	**Number of shares or units of stock that have not vested**	**Market value of shares or units of stock that have not vested**
Jeffrey Wolf	10,000 (1)	—	$ 86.20	06/11/2024	—	—
Chairman and	1,251 (2)	—	$ 45.30	1/12/2025	—	—
Chief Executive Officer	9,406 (3)	—	$ 24.70	1/11/2026	—	—
	5,495 (4)	2,005	$ 8.60	12/30/2026	—	—
	9,128 (5)	3,373	$ 8.70	1/03/2027	6,250 (6)	3,000 (6)
	28,544 (7)	31,016	$ 3.97	1/07/2028	20,250 (8)	$ 9,720 (8)
	400,000 (9)	400,000	$ 1.06	1/02/2029	400,000 (10)	$ 192,000 (10)
	—	—	0.46	12/30/2029	450,000 (11)	$ 216,000 (11)
Jeff T. Hutchins	14,583 (12)	5,417	$ 8.70	1/03/2027	—	—
Chief Scientific Officer and	6,458 (13)	3,542	$ 6.60	6/28/2027	—	—
Chief Operating Officer	14,206 (14)	15,442	$ 3.97	1/08/2028	—	—
	178,430 (15)	178,430	$ 1.06	1/02/2029	71,570 (16)	$ 34,354 (16)
Ann A. Rosar	1,000 (17)	—	$ 45.30	1/12/2025	—	—
Former Vice President of	489 (18)	—	$ 24.70	1/11/2026	—	—
Finance, Controller	1,500 (19)	—	$ 6.60	4/5/2026	—	—
and Secretary	3,791 (20)	—	$ 8.70	1/03/2027	—	—
	1,093 (21)	—	$ 6.60	6/28/2027	—	—
	1,930 (22)	4,688	$ 3.97	1/08/2028	—	—
William L. Ostrander	4,687 (23)	70,313	$ 0.52	9/25/2029	—	—
Vice President of						
Finance and Secretary						

(1) All shares are fully vested as of January 2016.
(2) All shares are fully vested as of December 2018.
(3) All shares are fully vested as of December 2019.
(4) Issued on December 30, 2016, these options vest over a four-year period and fully vested in January 2020.
(5) Issued on January 3, 2017, these shares vest over a 46-month period and will be fully vested in January 2021.
(6) Issued on January 3, 2017, 3,125 restricted stock units vested January 3, 2018; 3,125 restricted stock units vested January 3, 2019; 3,125 restricted stock units vest January 3, 2020, and 3,125 restricted stock units vest January 3, 2021. Market value based on closing price of the common stock of $0.48 on December 31, 2019.
(7) Issued on January 7, 2018, these shares vest over a 46-month period and will be fully vested in January 2022.
(8) Issued on January 7, 2018, 10,125 restricted stock units vested January 8, 2018; 10,125 vested January 8, 2019; 10,125 vest January 7, 2020; and 10,125 vest January 8, 2021. Amount represents the value of shares at December 31, 2019. Market value based on closing price of the common stock of $0.48 on December 31, 2019.
(9) Issued on January 2, 2019, 400,000 shares vested on January 2, 2019; 240,000 shares vest January 2, 2020; 80,000 shares vest January 2, 2021; and 80,000 shares vest January 2, 2022.
(10) Issued on January 2, 2019, 400,000 restricted stock units vested January 2, 2019; 240,000 vest January 2, 2020; 80,000 vest January 2, 2021; and 80,000 vest January 2, 2022. Market value based on closing price of the common stock of $0.48 on December 31, 2019.
(11) Issued on December 30, 2019, 450,000 restricted stock units vested December 30, 2019; 270,000 vest December 30, 2020; 90,000 vest December 30, 2021; and 90,000 vest December 30, 2022. Market value based on closing price of the common stock of $0.48 on December 31, 2019.

(12) Issued on January 3, 2017, these shares vest over a 46-month period and will be fully vested in January 2021.
(13) Issued on June 28, 2017, these shares vest over a 46-month period and will be fully vested in May 2021.
(14) Issued on January 7, 2018, these shares vest over a 46-month period and will be fully vested in January 2022.
(15) Issued on January 2, 2019, 178,430 shares vested on January 2, 2019; 107,058 shares vest January 2, 2020; 35,686 shares vest January 2, 2021; and 35,686 shares vest January 2, 2022.
(16) Issued on January 2, 2019, 71,570 restricted stock units vested January 2, 2019; 42,942 vest January 2, 2020; 14,314 vest January 2, 2021; and 14,314 vest January 2, 2022. Market value based on closing price of the common stock of $0.48 on December 31, 2019.
(17) Issued January 12, 2015, these shares vest over a four-year period and were fully vested in January 2019.
(18) Issued January 11, 2016, these shares vest over a four-year period and 489 shares fully vested through the period of resignation March 2019.
(19) Issued April 15, 2016, these shares vest over a four-year period and 1,500 shares fully vested through the period of resignation in March 2019.
(20) Issued January 3, 2017, these shares vest over a 46-month period and 3,791 shares fully vested through the period of resignation March 2019.
(21) Issued June 28, 2017, these shares vest over a 46-month period and 1,093 shares fully vested through the period of resignation March 2019.
(22) Issued January 7, 2018, these shares vest over a 46-month period and 1,930 shares fully vested through the period of resignation March 2019.
(23) Issued September 25, 2019, these shares vest over a 48-month period and will be fully vested in September 2023.

The chart above does not include the grant on January 2, 2020 of (i) restricted stock awards for 1,980,000 issued to Mr. Wolf which vest 50% on grant date, 30% on the one year anniversary of the grant date, 10% shall vest on the two-year anniversary of the grant date, and the remaining 10% shall vest on the three-year anniversary of the grant date and expire (10) years from the date of the grant, unless terminated earlier; (ii) options exercisable for 150,000 shares of common stock issued to each Dr. Monahan and Mr. Smith.

Employment Agreements

On December 18, 2009, we entered into an employment agreement with Jeffrey Wolf to act as our Chief Executive Officer, which agreement was amended on November 22, 2011, and further amended on each of January 20, 2014, January 11, 2016, January 1, 2017 and January 2, 2020. Mr. Wolf receives an annual base salary of $440,406 per year. He also may receive, at the sole discretion of the board, an additional cash performance-based bonuses equal to up to 50% of his then outstanding base salary at the end of each year and a discretionary equity award, with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. In addition, he is to receive certain options to purchase 2% of our fully diluted equity at an exercise price equal to the then current market price if our stock is traded on a nationally recognized exchange or Nasdaq and our market capitalization is at least $250 million for at least 5 days. If Mr. Wolf's employment contract is terminated for death or disability (as defined in the agreement), he (or his estate in the event of death) will receive six month's severance. If Mr. Wolf's employment is terminated by us other than for cause, he will receive 12 month's severance. In addition, if Mr. Wolf's employment is terminated by us other than for cause all restricted shares, common stock and options to purchase common stock that would have vested shall immediately vest. Mr. Wolf will not be entitled to any additional severance in the event he is terminated for cause or voluntarily resigns. Under his employment agreement, Mr. Wolf has also agreed to non-competition provisions.

On January 2, 2017, we approved the entry for a four-year employment agreement, effective as of January 1, 2017, with Jeff T. Hutchins, Ph.D., which agreement was amended on June 29, 2017, January 1, 2018, January 1, 2019 and January 2, 2020 (collectively, the "Hutchins Employment Agreement"), who was initially appointed to serve as the Chief Scientific Officer and Senior Vice President of Pre-Clinical Development of the Company. Pursuant to the Hutchins Employment Agreement that was amended on June 29, 2017, Dr. Hutchins was appointed to serve as both Chief Scientific Officer and Chief Operating Officer. Pursuant to the Hutchins Employment Agreement, as amended, Dr. Hutchins is entitled to an annual base salary of $353,676 and will be eligible for a cash performance bonus equal to approximately 30% of his then outstanding base salary at the end of each year in addition to an equity bonus in the sole discretion of Board, with the actual amount of any such bonus increased or decreased in the sole discretion of the Board.

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

Effective September 24, 2019, Mr. Ostrander became our Vice President of Finance and Secretary. Pursuant to our offer letter, as amended on January 2, 2020 Mr. Ostrander is entitled to an annual base salary of $226,600 and is eligible to receive an annual bonus of up to 20% of his annual salary. In addition, Mr. Ostrander was granted 75,000 incentive stock options to purchase shares of common stock that vests pro rata over four (4) years. Mr. Ostrander will also be eligible for other benefits consistent with those received by our other executives.

On April 5, 2016, we entered into a four-year employment agreement with Ann A Rosar to serve as our Vice President of Finance, Controller and Corporate Secretary, which agreement was amended on January 1, 2017, June 29, 2017 and January 1, 2018 (collectively, the "Rosar Employment Agreement"). Pursuant to the Rosar Employment Agreement, as amended, Ms. Rosar received an annual base salary of $266,500 and was eligible for a discretionary performance bonus. In addition, Ms. Rosar's agreement provided that if her employment was terminated for any reason, she or her estate as the case may be, would be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by her to the extent not previously paid ("Rosar Accrued Obligations"); provided, however, that if her employment was terminated without Just Cause (as defined in the employment agreement) or by Ms. Rosar for Good Reason (defined as a material breach of the terms of the employment agreement by us, which breach is not cured within thirty (30) days) then in addition to paying the Accrued Obligations, we were obligated to continue to pay her then current base salary for a period of four (4) months.

Ms. Rosar resigned as our Vice President of Finance and on March 7, 2019, we entered into an agreement pursuant to which, among other things, she was retained as our consultant, effective as of April 30, 2019 through December 31, 2019. In consideration of her continued services as a consultant, Ms. Rosar was paid her current monthly employee compensation for services performed for the month of April, an hourly rate thereafter for providing consulting services, will receive payment for unused paid time off and all vested options at the expiration of her provision of services will terminate five years from the date of grant (subject to her execution of a general release).

From April 1, 2019 until September 20, 2019, Robert J. Jakobs, served as our Vice President of Finance and Secretary. Mr. Jakobs joined our company on March 4, 2019 as Controller. Pursuant to our offer letter with Mr. Jakobs, Mr. Jakobs was entitled to an annual base salary of $220,000 and was eligible to receive an annual bonus of up to 20% of his annual salary. In addition, Mr. Jakobs was granted 75,000 incentive stock options to purchase shares of common stock vesting pro rata over four (4) years. Mr. Jakobs was also be eligible for other benefits consistent with those received by our other executives. On September 20, 2019, we entered into a separation agreement with Mr. Jakobs providing for, among other things, termination of Mr. Jakobs' employment as the Company's Vice President of Finance and a severance benefit equal to one months' payment.

2019 Director Compensation

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2019 regarding the compensation of our directors who at December 31, 2019 were not also named executive officers.

Name and Principal Position	Fees Earned or Paid in Cash	Option Awards	Stock Awards	Totals
John Monahan, PhD (1)	$ 61,500	$ 114,780	$ —	$ 176,280
John K. A. Prendergast, PhD (2)	$ 221,000	$ —	$ 318,000	$ 539,000
Edward Smith (1)	$ 72,500	$ 115,350	$ —	$ 187,850

(1) The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to purchase 150,000 shares of common stock granted on January 2, 2019 to each individual board member with 50% vesting on grant date, 30% vesting on the one year anniversary of the grant date and 10% vesting on the second and third year anniversaries of the grant date, subject to continued service as a board member through such date. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2019 and 2018.

(2) Restricted stock awards are computed in accordance with FASB ASC 718 and reflect the aggregate grant date fair value of 300,000 shares granted on January 2, 2019 with 50% vesting on grant date, 30% vesting on the one year anniversary of the grant date and 10% vesting on the second and third year anniversary of the grant date, subject to continued service as a board member through such date. The fair value of the restricted stock is based on the closing stock price of an unrestricted share of the Company's common stock on the grant date. As of December 31, 2019, 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	Aggregate Number of Stock Awards
John Monahan, Ph.D.	175,018	–
John K. A. Prendergast, Ph.D.	41,059	300,000
Edward Smith	174,257	–

Our Compensation Committee conducted an evaluation of the compensation of the members of our board of directors with assistance from Korn Ferry. As described in additional detail above under “Executive Compensation,” Korn Ferry is the Compensation Committee’s independent compensation advisor and was engaged to provide analysis, guidance and considerations pursuant to our director pay program. Based on Korn Ferry’s review last year, the Compensation Committee determined that the director pay program was consistent with competitive market practices (relative to Heat Biologic’s publicly-traded peer group at that time), aligned with our overall philosophy and approach to director pay and reflective of desired competitive positioning. During the year ended December 31, 2019, and anticipated to remain the same for 2020, directors who are not employees receive an annual cash fee of $35,000 as well as a cash fee of $8,000 for service on the Audit Committee and $5,000 for service on each of the Compensation Committee and the Nominating and Governance Committee. In addition, the Chairman of each of the Audit, Compensation and Nominating and Governance Committees will each receive an additional cash fee of $12,500, $8,500 and $7,000, respectively. The lead independent director receives a monthly fee of $14,000 for his services as lead independent director.

The following stock option and awards are excluded from the above table. Due to the price of our common stock, it was determined that the equity portion of our director pay program was not consistent with competitive market practices (relative to our publicly-traded peer group at that time). Accordingly, on January 2, 2020, after consultation with Korn Ferry, Dr. Monahan and Mr. Smith received an option grant each to purchase 150,000 shares of our common stock vesting 50% immediately, 30% on the one-year anniversary of the grant date, 10% shall vest on the two-year anniversary grant date, and the remaining 10% shall vest on the three-year anniversary grant date. These stock option grants provided to Dr.

Monahan and Mr. Smith will expire (10) years from the date of the grant, unless terminated earlier. For his services as lead independent director Dr. Prendergast received a grant of 400,000 restricted shares of common stock vesting 50% immediately, 30% on the one-year anniversary of the grant date, 10% shall vest on the two-year anniversary of the grant date, and the remaining 10% shall vest on the three-year anniversary of the grant date.

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

The following table sets forth information, as of March 30, 2020, 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 23, 2020, we had 79,384,021 shares of common stock outstanding.

Security Ownership of Management and Certain Beneficial Owners

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 627 Davis Drive, Suite 400, Morrisville, North Carolina 27560. 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				
Jeff T. Hutchins (Chief Scientific Officer and Chief Operating Officer)	143,140 (2)	347,572	490,712	*
John Monahan, Ph.D. (Director)	516	220,018	220,534	*
William L. Ostrander (Vice President of Finance and Secretary)	—	17,187	17,187	*
John K. A. Prendergast, Ph.D. (Director)	700,000 (3)	41,059	741,059	*
Ann A. Rosar (Former Vice President of Finance, Controller and Secretary)	51,539 (4)	64,088	115,627	*
Robert Jakobs (Former Vice President of Finance)	—	—	—	*
Edward Smith (Director) (5)	104,305	219,257	323,562	*
Jeffrey Wolf (Chairman of the Board of Directors, Chief Executive Officer and President) (6)	3,917,763 (7)	711,868	4,629,631	5.8 %
All Executive Officers and Directors, as a group (8 persons)	4,917,263	1,621,049	6,538,312	8.1 %
5% or Greater Stockholders				
Sabby Volatility Warrant Master Fund, Ltd (8)	4,300,000 (8)	—	4,300,000	5.4 %

* less than 1%

(1) Represents shares subject to options that are currently vested and options that will vest and become exercisable within 60 days of March 31, 2019.
(2) Includes 28,628 unvested shares received pursuant to a restricted stock award granted in January 2019.
(3) Includes 260,000 unvested shares received pursuant to restricted stock awards granted in January 2019 and January 2020 that are subject to forfeiture.
(4) Includes a 89,430 Restricted Stock Award granted January 2019 of which 44,715 was forfeited and 6,824 owned by Ms. Rosar.
(5) Includes 103,304 shares of common stock owned by Aristar Capital Management, LLC, an entity of which Mr. Smith is the managing member and exercises investment discretion. Mr. Smith disclaims beneficial ownership of the 103,304

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 77,172 shares of common stock held by Orion Holdings V, LLC and 71,620 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 26,468 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) Includes 1,600,000 unvested shares received pursuant to restricted stock awards granted in January 2018, January 2019, December 2019, and January 2020 that are subject to forfeiture.

(8) Pursuant to a Schedule 13G filed by Sabby Volatility Warrant Master Fund, Ltd., Sabby Management, LLC and Hal Mintz on January 23, 2020, Sabby Management, LLC is the investment manager of Sabby Volatility Warrant Master Fund, Ltd. Hal Mintz is the Manager of Sabby Management, LLC and in such capacity has the right to vote and dispose of the securities held by Sabby Volatility Warrant Master Fund, Ltd. The address of Sabby Volatility Warrant Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. The address of Sabby Management, LLC is 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458. The address of Hal Mintz is c/o Sabby Management, LLC, 10 Mountainview Road, Suite 205, Upper Saddle River, New Jersey 07458.

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, 2018 to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the sections of this Annual Report on Form 10-K entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—2019 Director Compensation" and Part III, Item 11. "Executive Compensation:"

Compensation paid to our executive officers during 2018 and 2019, equity awards granted to our executive officers and directors during 2018 and on January 2, 2019, as well as the terms of our consulting arrangement with Ann Rosar are disclosed under the sections of this Annual Report on Form 10-K entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—2019 Director Compensation" and Part III, Item 11. "Executive Compensation."

Indemnification agreements

Our third amended and restated certificate of incorporation contains provisions limiting the liability of directors and our amended and restated bylaws provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. In addition, we have entered and expect to continue to enter into agreements to indemnify our directors.

Independence of the Board of Directors

The board of directors undertook a review of the independence of the members of the board of directors and considered whether any director has a material relationship with our company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the board of directors has determined that all of our current directors, except Mr. Wolf, due to his position as President and Chief Executive Officer of our company, is "independent" as that term is defined under the rules of Nasdaq. As a result, Dr. Monahan, Dr. Prendergast and Mr. Smith are deemed to be "independent" as that term is defined under the rules of Nasdaq. See the section of this Annual Report on Form 10-K entitled "Item 10. Directors, Executive Officers and Corporate Governance."

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, 2019 and 2018 by BDO USA, LLP.

	December 31, 2019	December 31, 2018
Audit Fees and Expenses (1)	$ 321,175	310,000

(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, 2019 and 2018:

1. Report of Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2019 and 2018
3. Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018
4. Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018
5. Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018
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 exhibits set forth in the accompanying exhibit index below are either filed as part of this report or are incorporated herein by reference:

Item 16. *Form 10-K Summary*

Not applicable.

Exhibit No.	Description
1.1	Common Stock Sales Agreement, dated January 18, 2018, by and between Heat Biologics, Inc. and H.C. Wainwright & Co., LLC (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 19, 2018 (File No. 001-35994))
1.2	At Market Issuance Sales Agreement, dated April 3, 2019, by and between Heat Biologics, Inc. and B. Riley FBR, Inc. (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 4, 2019 (File No. 001-35994))
3.1	Third Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on May 29, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 17, 2017 (File No. 001-35994))
3.4	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 19, 2018 (File No. 001-35994))
3.5	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (previously filed as an exhibit to the Current Report on Form 8 K with the Securities and Exchange Commission March 23, 2018 (File No. 001 35994))
3.6	Amended and Restated Bylaws, dated October 17, 2019 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on October 18, 2019 (File No. 001-35994))
3.7	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. (previously filed as an exhibit to the Current Report on Form 8 K with the Securities and Exchange Commission on March 23, 2020 (File No. 001 35994))
4.1	2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.2	First Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.3	Second Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.4	Third Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.5	Fourth Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.6	Specimen Common Stock Certificate of Heat Biologics, Inc. (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.7	Form of Stock Purchase Agreement by and among Heat Biologics, Inc. and the Series B investors (Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions have been filed with the Commission) ## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.8	2014 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on June 13, 2014 (File No. 333-196763))
4.9	Amended and Restated Heat Biologics, Inc. 2014 Stock Incentive Plan## (previously filed as Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 22, 2015))
4.10	Form of Warrant (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 3, 2016 (File No. 001-35994))
4.11	2017 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on July 11, 2017 (File No. 333-219238))

4.12	Rights Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated March 11, 2018 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 12, 2018 (File No. 001-35994))
4.13	2018 Stock Incentive Plan (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
4.14	Warrant Agency Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated May 2, 2018 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))
4.15	Common Stock Purchase Warrant (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))
4.16	Form of Warrant (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on November 21, 2018 (File No. 001-35994))
4.17	Amendment No. 1 to Rights Plan (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2019 (File No. 001-35994))
4.18	Amendment No. 2 to the Rights Agreement dated as of March 10, 2020 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to the Registration Statement on Form 8-A/A filed with the Securities and Exchange Commission on March 13, 2020 (File No. 001-35994))
4.19	Form of Warrant (previously filed as an exhibit to Heat Biologic, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2020 (File No. 001-35994)
4.20	Description of Securities of Heat Biologics, Inc.*
10.1	License Agreement (UMJ110) between the University of Miami and Heat Biologics, Inc. effective February 18, 2011** (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.2	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008**(previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.3	License Agreement (143) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 11, 2011** (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.4	License Agreement (D-107) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011** (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.5	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011** (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.6	Common Stock Subscription Agreement between the University of Miami and Heat Biologics I, Inc. dated July 7, 2009 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.7	Employment Agreement with Jeffrey Wolf dated December 18, 2009## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.8	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.9	Non-Exclusive Evaluation and Biological Material License Agreement with American Type Culture Collection effective April 12, 2011** (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.10	Manufacturing Services Agreement with Lonza Walkersville, Inc. dated as of October 20, 2011 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.11	Assignment and Assumption Agreement dated June 26, 2009 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.12	Termination Agreement UM97-114 dated June 26, 2009 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.13	Amendment to License Agreement (UM97-14) dated April 29, 2009 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.14	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.15	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.16	Amendment to Employment Agreement, dated as of January 20, 2014 between the Company and Jeffrey Wolf## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994))
10.17	Lease Agreement dated January 24, 2014 (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2014 (File No. 001-35994))
10.18	License Agreement (UMK-161) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective March 4, 2014** (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2014 (File No. 001-35994))
10.19	First Amendment to Lease (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 27, 2015 (File No. 001-35994))
10.20	Second Amendment to Lease (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 27, 2015 (File No. 001-35994))
10.21	Form of Incentive Stock Option Agreement under the 2014 Stock Incentive Plan, as amended## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.22	Form of Non-Statutory Stock Option Agreement under the 2014 Stock Incentive Plan, as amended## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.23	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 11, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))

10.24	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated April 1, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
10.25	Employment Agreement between the Company and Ann Rosar, dated April 1, 2016 ## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
10.26	Amendment to License Agreement (UM97-14) between the University of Miami and Heat Biologics, Inc. effective July 26, 2016 (previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.27	Form of Indemnification Agreement by and between Heat Biologics, Inc. and its directors and officers (previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.28	Exclusive License Agreement (UMIP-114/Strbo) between the University of Miami and Zolovax, Inc., a wholly-owned subsidiary of Heat Biologics effective October 24, 2016 (previously filed as an exhibit to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on November 10, 2016 (File No. 001-35994))
10.29	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 1, 2017## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994)
10.30	Amendment to Employment Agreement between the Company and Ann Rosar, dated January 1, 2017## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.31	Employment Agreement between the Company and Jeff T. Hutchins, dated January 1, 2017## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.32	Form of Restricted Stock Unit Award Agreement## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.33	Stock Purchase Agreement by and among Heat Biologics, Inc., with Pelican Therapeutics, Inc. ("Pelican"), and certain stockholders in Pelican (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 8, 2017 (File No. 001-35994))
10.34	First Amendment to Exclusive License Agreement between The Regents of The University of Michigan and Heat Biologics, Inc. (UM File Number 3680) dated December 1, 2016 (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.35	First Amendment to Stock Purchase Agreement dated March 29, 2017 by and among Heat Biologics, Inc., Pelican Therapeutics, Inc. and Josiah Hornblower as representative of the Stockholders (previously filed as an exhibit to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.36	Funding Commitment issued by Heat Biologics, Inc. dated April 6, 2017 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 7, 2017 (File No. 001-35994)
10.37	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated July 11, 2008 (UM03-31, UM05-39)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.38	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated December 12, 2010 (UMI176)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.39	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated November 19, 2013 (UM-143 and UMN-106)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017) (File No. 001-35994))
10.40	Amendment to License Agreement between Heat Biologics, Inc. and University of Miami dated April 20, 2009** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.41	Assignment and Assumption Agreement between Heat Biologics, Inc. and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated June 26, 2009 (UM03-31, UM05-39)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.42	Second Amendment to License Agreement between Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) and University of Miami dated August 11, 2009 (UM03-31, UM05-39)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.43	Payment Agreement between Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated December 19, 2012 (UMI176)** (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.44	CPRIT Grant (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017** (File No. 001-35994))
10.45	Amendment to Employment Agreement with Jeff T. Hutchins dated as of June 29, 2017## (filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 30, 2017 (File No. 001-35994))
10.46	Amendment to Employment Agreement with Ann Rosar dated as of June 29, 2017## (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 30, 2017 (File No. 001-35994))
10.47	Amendment to Employment Agreement with Jeff T. Hutchins dated as of January 1, 2018## (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2018 (File No. 001-35994))
10.48	Amendment to Employment Agreement with Ann Rosar dated as of January 1, 2018## (previously filed as an exhibit 1to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2018 (File No. 001-35994))
10.49	Form of Incentive Stock Option Agreement under the 2017 Stock Incentive Plan## (previously filed as an exhibit 1to Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.50	Form of Non-Statutory Stock Option Agreement under the 2017 Stock Incentive Plan## (previously filed as an exhibit 1to Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.51	Form of Restricted Stock Unit Award Agreement under the 2017 Stock Incentive Plan## (previously filed as an exhibit 1to Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))

10.52	Form of Incentive Stock Option Agreement under the 2018 Stock Incentive Plan (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.53	Form of Non-Statutory Stock Option Agreement under the 2018 Stock Incentive Plan (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.54	Form of Notice of Award under the 2018 Stock Incentive Plan (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.55	Form of Restricted Stock Agreement under the 2018 Stock Incentive Plan (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.56	Amendment to Employment Agreement between Heat Biologics, Inc. and Jeffrey T. Hutchins, effective as of January 1, 2019 ## (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2019 (File No. 001-35994))
10.57	Heat Biologics, Inc. Form of Restricted Stock Agreement (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2019 (File No. 001-35994))
10.58	Agreement with Ann Rosar dated March 7, 2019## (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2019 (File No. 001-35994))
10.59	Offer Letter with Bob Jakobs dated March 7, 2019## (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2019 (File No. 001-35994))
10.60	Attachment F to CPRIT Contract (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2019 (File No. 001-35994))
10.61	Lease between Durham KTP Tech 7, LLC and Heat Biologics, Inc. dated April 17, 2019 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2019 (File No. 001-35994))
10.62	Amendment No. 1 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (previously filed as Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 4, 2019)
10.63	Agreement by and between Heat Biologics, Inc. and Robert J. Jakobs, dated September 20, 2019 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2019 (File No. 001-35994))
10.64	Offer Letter by and between Heat Biologics, Inc. and William L. Ostrander, dated September 23, 2019 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2019 (File No. 001-35994))
10.65	Attachment F to CPRIT Contract (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on November 22, 2019 (File No. 001-35994))
10.66	Amendment to Employment Agreement between Heat Biologics, Inc. and Jeffrey Wolf, effective as of January 1, 2020 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.67	Amendment to Employment Agreement between Heat Biologics, Inc. and Jeffrey T. Hutchins, effective as of January 1, 2020 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.68	Amendment to Offer Letter between Heat Biologics, Inc. and William Ostrander, effective as of January 1, 2020 (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.69	Form of Restricted Stock Agreement (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.70	Form of Investor Agreement (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2020 (File No. 001-35994))
10.71	Amendment no. 2 to the Heat Biologics 2018 Stock Incentive Plan (previously filed as Appendix D to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on January 24, 2020)
10.72	Form of Exchange Agreement (previously filed as an exhibit to Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on March 3, 2020 (File No. 001-35994))
21.1	List of Subsidiaries *
23.1	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP)*
31.1	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) *
31.2	Certification of William Ostrander Principal Financial Officer and Principal Accounting Officer pursuant to Rule 13a-14(a)/15d-14(a) *
32.1	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *
32.2	Certification of William Ostrander, Principal Financial Officer and Principal Accounting Officer pursuant to Section 1350 of the Sarbanes-Oxley Act of 2002 *
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *

* 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 to this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 30th day of March 2020.

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Jeffrey Wolf
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)
Date: March 30, 2020

By: /s/ William Ostrander
William Ostrander
Vice President of Finance, and Secretary
(Principal Financial and Principal Accounting Officer)
Date: March 30, 2020

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Wolf, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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 of the Board (Principal Executive Officer)	March 30, 2020
/s/ William L. Ostrander William L. Ostrander	Vice President of Finance, and Secretary (Principal Financial and Principal Accounting Officer)	March 30, 2020
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 30, 2020
/s/ John K.A. Prendergast, Ph.D. John K.A. Prendergast, Ph.D.	Director	March 30, 2020
/s/ Edward B. Smith Edward B. Smith	Director	March 30, 2020

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors
Heat Biologics, Inc.
Morrisville, North Carolina

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Heat Biologics, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Notes 2 and 13 to the consolidated financial statements, the Company changed its method of accounting for leases in the year ended December 31, 2019 upon adoption of Accounting Standards Codification (ASC) Topic 842, Leases, using the modified retrospective method.

Going Concern Uncertainty

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.

Raleigh, North Carolina
March 30, 2020

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Current Assets		
Cash and cash equivalents	$ 9,039,887	$ 22,154,251
Short-term investments	5,713,922	5,570,027
Accounts receivable	34,986	28,538
Prepaid expenses and other current assets	420,328	961,317
Total Current Assets	15,209,123	28,714,133
Property and Equipment, net	559,410	643,146
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	2,189,338
Operating lease right-of-use asset	2,287,500	—
Finance lease right-of-use asset	187,573	—
Deposits	394,637	351,220
Total Other Assets	10,188,048	8,406,558
Total Assets	$ 25,956,581	$ 37,763,837
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,503,342	$ 974,619
Deferred revenue, current portion	3,410,319	1,032,539
Contingent consideration, current portion	1,579,334	1,187,000
Operating lease liability, current portion	216,832	—
Finance lease liability, current portion	49,104	—
Accrued expenses and other liabilities	1,676,467	1,678,051
Total Current Liabilities	8,435,398	4,872,209
Long Term Liabilities		
Other long-term liabilities	—	213,724
Deferred tax liability	361,911	316,733
Deferred revenue, net of current portion	200,000	200,000
Operating lease liability, net of current portion	1,519,574	—
Financing lease liability, net of current portion	142,667	—
Contingent consideration, net of current portion	2,139,181	1,918,225
Total Liabilities	12,798,731	7,520,891
Commitments and Contingencies (Note 9 and 13)		
Stockholders' Equity		
Common stock, $.0002 par value; 100,000,000 shares authorized, 33,785,999 and 32,492,144 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	6,757	6,499
Additional paid-in capital	118,173,843	114,883,135
Accumulated deficit	(104,597,748)	(84,580,180)
Accumulated other comprehensive loss	(11,250)	(19,904)
Total Stockholders' Equity - Heat Biologics, Inc.	13,571,602	30,289,550
Non-Controlling Interest	(413,752)	(46,604)
Total Stockholders' Equity	13,157,850	30,242,946
Total Liabilities and Stockholders' Equity	$ 25,956,581	$ 37,763,837

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31, 2019	Year ended December 31, 2018
Revenue:		
Grant and licensing revenue	$ 3,049,104	$ 5,793,849
Operating expenses:		
Research and development	13,013,604	16,233,014
General and administrative	9,431,015	7,025,212
Goodwill impairment loss	737,000	—
Change in fair value of contingent consideration	613,290	495,936
Total operating expenses	23,794,909	23,754,162
Loss from operations	(20,745,805)	(17,960,313)
Interest income	431,824	265,752
Other (expense) income, net	(25,557)	117,780
Total non-operating income	406,267	383,532
Net loss before income taxes	(20,339,538)	(17,576,781)
Income tax (expense) benefit	(45,178)	985,488
Net loss	(20,384,716)	(16,591,293)
Net loss - non-controlling interest	(367,148)	(857,439)
Net loss attributable to Heat Biologics, Inc.	$ (20,017,568)	$ (15,733,854)
Net loss per share attributable to Heat Biologics, Inc.-		
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	$ (0.60)	$ (0.90)
Weighted-average number of common shares used in net loss per share attributable to common stockholders -		
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted	33,281,817	17,485,461
Other comprehensive loss:		
Net loss	(20,384,716)	(16,591,293)
Unrealized gain on foreign currency translation	8,654	146,121
Total other comprehensive loss	(20,376,062)	(16,445,172)
Comprehensive loss attributable to non-controlling interest	(367,148)	(857,439)
Comprehensive loss	$ (20,008,914)	$ (15,587,733)

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS INC.
Consolidated Statements of Stockholders' Equity

	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Non-Controlling Interest	Total Stockholders Equity
Balance at December 31, 2017	$ 840	$ 76,382,262	$ (68,846,326)	$ (166,025)	$ (1,589,842)	$ 5,780,909
Public offering, 14,375,000 shares, net of underwriters discounts	2,875	20,697,122	—	—	—	20,699,997
Public offering, 9,200,000 shares, net of underwriters discounts	1,840	13,798,160	—	—	—	13,800,000
Exercise of warrants, 3,054,667 shares	611	4,837,982	—	—	—	4,838,593
Issuance of common stock, 1,566,997	314	3,909,779	—	—	—	3,910,093
Acquisition of non-controlling interest of Heat I/Pelican	7	(2,400,684)	—	—	2,400,677	—
Stock issuance costs	—	(3,130,133)	—	—	—	(3,130,133)
Stock-based compensation	12	788,647	—	—	—	788,659
Other comprehensive income	—	—	—	146,121	—	146,121
Net loss	—	—	(15,733,854)	—	(857,439)	(16,591,293)
Balance at December 31, 2018	6,499	114,883,135	(84,580,180)	(19,904)	(46,604)	30,242,946
Issuance of common stock, 90,300 shares	18	18,880	—	—	—	18,898
Exercise of stock options, 2,000 shares	—	2,120	—	—	—	2,120
Issuance of common stock from vesting of restricted stock awards, 1,201,555 shares	240	(240)	—	—	—	—
Stock based compensation	—	3,269,948	—	—	—	3,269,948
Other comprehensive loss	—	—	—	8,654	—	8,654
Net loss	—	—	(20,017,568)	—	(367,148)	(20,384,716)
Balance at December 31, 2019	$ 6,757	$ 118,173,843	$ (104,597,748)	$ (11,250)	$ (413,752)	$ 13,157,850

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
Consolidated Statements of Cash Flows

	For the year ended December 31,	
	2019	**2018**
Cash Flows from Operating Activities		
Net loss	$ (20,384,716)	$ (16,591,293)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment loss	737,000	—
Depreciation and amortization	232,506	237,318
Noncash lease expense	39,116	—
Noncash interest expense	954	
Loss on disposal of equipment	11,998	—
Stock-based compensation	3,269,948	788,659
Change in fair value of contingent consideration	613,290	495,936
Unrealized gain on investments	(5,457)	131
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	(6,472)	(14,094)
Prepaid expenses and other current assets	540,789	1,000,961
Deferred financing costs	—	30,000
Operating lease right-of-use asset	(590,210)	—
Accounts payable	529,269	(55,820)
Deferred revenue	2,377,780	(5,793,849)
Deferred tax liability	45,178	(985,487)
Accrued expenses and other liabilities	8,518	(595,896)
Other long-term liabilities	(213,724)	53,165
Deposits	(43,417)	(281,422)
Net Cash Used in Operating Activities	(12,837,650)	(21,711,691)
Cash Flows from Investing Activities		
Purchase of short-term investments	(138,438)	(5,570,158)
Purchase of property and equipment	(265,188)	(593,573)
Proceeds from sale of property and equipment	109,630	—
Net Cash Used in Investing Activities	(293,996)	(6,163,731)
Cash Flows from Financing Activities		
Proceeds from public offering, net of underwriting discounts	—	34,499,997
Proceeds from the issuance of common stock, net of commissions	18,898	3,910,093
Proceeds from exercise of stock options	2,120	—
Proceeds from exercise of warrants	—	4,838,593
Stock issuance costs	—	(3,130,133)
Repayments on principal of finance lease	(1,966)	—
Net Cash Provided by Financing Activities	19,052	40,118,550
Effect of exchange rate changes on cash and cash equivalents	(1,770)	145,764
Net (Decrease) Increase in Cash and Cash Equivalents	(13,114,364)	12,388,892
Cash and Cash Equivalents – Beginning of Period	22,154,251	9,765,359
Cash and Cash Equivalents – End of Period	$ 9,039,887	$ 22,154,251
Supplemental Disclosure for Cash Flow Information:		
Operating lease right-of-use assets obtained with lease liabilities	$ 1,945,617	$ —
Finance lease right-of-use assets obtained with lease liabilities	$ 192,783	$ —
Acquisition of non-controlling interest of Heat I/Pelican	$ —	$ 2,400,677

See Notes to Consolidated Financial Statements

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Heat Biologics is a biopharmaceutical company developing immunotherapies focused on activating a patient's immune system against cancer through T-cell activation and expansion. Our T-cell Activation Platform (TCAP), includes two variations for intradermal administration, Immune Pan-antigen Cytotoxic Therapy (ImPACT®) and Combination Pan-antigen Cytotoxic Therapy (ComPACT™). HS-110 (viagenpumatucel-L) is our first biologic product candidate in a series of proprietary ImPACT® based immunotherapies designed to stimulate a patient's own T-cells to destroy cancer. HS-130 is an allogeneic ("off-the-shelf") cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T-cells, with the potential to augment antigen-specific CD8+ T-cell response. To further augment antigen experienced T-cell activation and expansion, we are also developing PTX-35, a novel T-cell co-stimulator agonist antibody targeting TNFRSF25 for systemic administration. These programs are designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. We have completed recruiting patients in our Phase 2 HS-110 non-small cell lung cancer (NSCLC) trial, have dosed our first patient in our first Phase 1 clinical trial of HS-130 and anticipate clearance by the U.S. Food & Drug Administration (FDA) of an IND for our PTX-35 program in the second quarter of 2020. We are also providing pre-clinical, CMC development, and administrative support for these operations; while constantly focusing on protecting and expanding our intellectual property in areas of strategic interest.

In July 2019, we completed patient enrollment in our Phase 2 clinical trial for HS-110 in advanced NSCLC, that administered HS-110 in combination with either Bristol-Myers Squibb's anti-PD1 checkpoint inhibitor nivolumab (Opdivo®) or more recently, Merck & Co., Inc.'s (Merck's) anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®). We also announced interim results of this study in June 2019. We believe that this data may represent the first Phase 2 data showing clinical activity of a checkpoint inhibitor combination in NSCLC patients whose disease has progressed after prior treatment with a checkpoint inhibitor (CPI).

Our T-cell Activation Platform (TCAP), which includes a variation of two TCAPs, ImPACT ® and ComPACT ™, is designed to activate and expand tumor antigen specific "killer" T-cells to destroy a patient's cancer. By turning immunologically "COLD tumors HOT," we believe our platform will become an essential component of the immuno-oncology cocktail to enhance the effectiveness and durability of checkpoint inhibitors and other cancer therapies, thereby improving outcomes for those patients less likely to benefit from checkpoint inhibitors alone.

We believe the advantage of our approach is that our biologic agents deliver a broad range of tumor antigens that are unrecognized by the patient's immune system prior to the malignant rise of the patient's tumor. TCAP combines these tumor antigens with a powerful, naturally occurring immune adjuvant, gp96, to actively chaperone these antigens out of our non-replicating allogenic cell-based therapy into the local microenvironment of the skin. The treatment primes local natural immune recognition to activate T-cells to seek and destroy the cancer cells throughout the body. These TCAP agents can be administered with a variety of immuno-modulators to enhance a patient's immune response through ligand specific T-cell activation.

Unlike many other "patient specific" or autologous immunotherapy approaches, our drugs are fully allogenic, "off-the-shelf" products which means that we can administer them immediately without the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment based on these patient materials. Our TCAP product candidates are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. Because each patient receives the same treatment, we believe that our immunotherapy approach offers superior speed to initiation, logistical, manufacturing and importantly, cost benefits, compared to "personalized" precision medicine approaches.

Our ImPACT® platform is an allogenic cell-based, T-cell-stimulating platform that functions as an immune activator to stimulate and expand T-cells. The key component of this innovative immunotherapy platform is the dual functionality of the heat shock protein, gp96.

As a molecular chaperone, gp96 is typically found within the cell's endoplasmic reticulum and facilitates the folding of newly synthesized proteins for functionalized tasks. When a cell abnormally dies through necrosis or infection, gp96 is naturally released into the surrounding microenvironment. At this moment, gp96 becomes a Danger Associated Molecular Protein, or "DAMP", a molecular warning signal for localized innate activation of the immune system. In this context, gp96 serves as a potent adjuvant, or immune stimulator, via Toll-Like Receptor 4/2 (TLR4 and TLR2) signaling which serves to activate professional antigen presenting cells (APCs), such as dendritic cells that upregulate T-cell costimulatory ligands, major histocompatibility (MHC) molecules and immune activating cytokines. It is among the most powerful adjuvants found in the body and uniquely shows exclusive specificity to CD8+ "killer" T-cells through cross-presentation of the gp96-chaperoned tumor associated peptide antigens directly to MHC class I molecules for direct activation and expansion of CD8+ T-cells. Thus, gp96 plays a critical role in the mechanism of action for our T-cell activating platform immuno-therapies; mimicking necrotic cell death and activating a powerful, tumor antigen-specific T-cell immune response to attack the patient's cancer cells.

ComPACT™, our second TCAP, is a dual-acting immunotherapy designed to deliver antigen-driven T-cell activation and specific co-stimulation in a single product. ComPACT™ is designed to help unlock the body's natural defenses and builds upon ImPACT ® by providing specific co-stimulation to enhance T-cell activation and expansion. This technology has the potential to simplify combination immunotherapy development for oncology patients, as it is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L) as a single therapeutic, without the need for multiple, independent biologic products. The potential advantages of ComPACT™ include: (a) enhanced activation of antigen-specific CD8+ T-cells; (b) serving as a booster to expand the number of antigen-specific CD8+ and CD4+ T-cells compared to OX40L alone; (c) stimulation of T-cell memory function to remain effective in the body after treatment, even if the cancer comes back; (d) demonstration of less toxicity, as the source of cancer associated antigens and co-stimulator are supplied at the same time locally and the draining lymph nodes, which drive targeted, cancer specific immunity towards the tumor rather than throughout the body; and (e) a potential paradigm shift that is designed to simplify combination cancer immunotherapy versus systemic co-stimulation with conventional monoclonal antibodies (mAbs).

Pelican Therapeutics, Inc. ("Pelican"), our majority owned subsidiary, is a biotechnology company focused on the development of biologic based therapies designed to activate the immune system.

Pelican is developing an agonist mAb, PTX-35, against T-cell costimulatory receptor, TNFRSF25. PTX-35 has completed IND-enabling activities in preparation for a first-in-human (FIH) trial for an oncology indication. PTX-35 is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. TNFRSF25 agonism has been shown to provide highly selective and potent stimulation of antigen experienced 'memory' CD8+ cytotoxic T-cells, which are the class of long-lived T-cells capable of eliminating tumor cells in patients. Due to the preferential specificity of PTX-35 to antigen experienced CD8+ T-cells, this agent represents a promising candidate as a T-cell co-stimulator in cancer patients.

When combined in preclinical studies with ImPACT ® and ComPACT ™ platform immunotherapies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. Pelican is also developing other biologics that target TNFRSF25 for various immunotherapy approaches, including PTX-45, a human TL1A-lg like fusion protein designed as a shorter half-life agonist of TNFRSF25.

We have completed patient enrollment in our HS-110 Phase 2 combination immunotherapy trial, dosed our first patient in our first Phase 1 clinical trial of HS-130, advanced pre-clinical development of Pelican assets in anticipation of clearance by the FDA of an IND submission in the second quarter of 2020, and provided general and administrative support for these operations while protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any revenue from product sales since our inception. We expect to continue to incur significant expenses and to incur increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we (1) complete the ongoing clinical trials of our product candidates; (2) maintain, expand and protect our intellectual property portfolio; (3) seek to obtain regulatory approvals for our product candidates; (4) continue our research and development efforts; (5) add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and (6) operate as a public company

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

All share numbers in the consolidated financial statements and footnotes below have been adjusted for the one-for-ten reverse stock split effective January 19, 2018.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Heat Biologics, Inc. and its subsidiaries, Heat Biologics I, Inc. ("Heat I") Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd, Zolovax, Inc., Delphi Therapeutics, Inc., and Scorpion Biosciences, Inc. Additionally, beginning April 28, 2017 the accompanying consolidated financials include Pelican. As of December 31, 2019, there was no activity for Delphi Therapeutics, Inc. or Scorpion Biosciences, Inc. The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency of the foreign entities. Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders' equity. All significant intercompany accounts and transactions have been eliminated in consolidation. At December 31, 2019 and 2018, Heat held 100% controlling interest in Heat I. The December 31, 2019 and 2018 year-end financials include 85% controlling interest in Pelican. Heat accounts for its less than 100% interest in the consolidated financial statements in accordance with U.S. GAAP. Accordingly, the Company presents non-controlling interest as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss – non-controlling interest" in the consolidated statements of operations and comprehensive loss.

Liquidity and Going Concern

The Company has an accumulated deficit of $104.6 million as of December 31, 2019 and a net loss of approximately $20.4 million for the year ended December 31, 2019 and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. The consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company continues its research and development and advances its clinical trials of, and seek marketing approval for, its product candidates and as the Company continues to fund the Pelican matching funds required in order to access the CPRIT Grant. In addition, if the Company obtains marketing approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, the Company will need to obtain substantial additional funding in connection with its continuing operations. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs or any future commercialization efforts. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on the Company's current estimates, and the Company could use its available capital resources sooner than it currently expects. The Company is continually evaluating various cost-saving measures in light of its cash requirements in order to focus resources on its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so. Management has determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued.

Use of Estimates

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

Segments

The Company has one reportable segment – the development of immunotherapies designed to activate and expand a patient's T-cell mediated immune system against cancer.

Cash and Cash Equivalents and Restricted Cash

The Company considers all cash and other highly liquid investments with initial maturities from the date of purchase of three months or less to be cash and cash equivalents.

Concentration of Credit Risk

At times, cash balances may exceed the Federal Deposit Insurance Corporation ("FDIC") insurable limits. The Company has never experienced any losses related to these balances. As of December 31, 2019 and 2018, cash amounts in excess of $250,000 were not fully insured. The uninsured cash balance as of December 31, 2019 was $8,474,836. The Company does not believe it is exposed to significant credit risk on cash and cash equivalents.

Property and Equipment

Property and equipment are stated at cost and are capitalized. Depreciation is calculated using the straight-line method and is based on estimated useful lives of five years for lab equipment, three years for computer equipment, and eight years for both furniture and fixtures and leasehold improvements.

Net Loss per Share

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

Fair Value of Financial Instruments

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued expenses and other payables approximate fair value due to their short maturities.

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

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

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

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

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. Assets and liabilities measured at fair value are classified in their entirety

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability. The Company's cash equivalents are classified within Level I of the fair value hierarchy.

As of December 31, 2019 and 2018, the fair values of cash, accounts payable, and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The Company's short-term investments consist of Level I securities which are comprised of highly liquid money market funds. The estimated fair value of the short-term investments was based on quoted market prices. There were no transfers between fair value hierarchy levels during the years ended December 31, 2019 or 2018.

The fair value of financial instruments measured on a recurring basis is as follows:

	As of December 31, 2019			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 5,713,922	$ 5,713,922	—	—
Liabilities:				
Contingent consideration	$ 3,718,515	—	—	$ 3,718,515

	As of December 31, 2018			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 5,570,027	$ 5,750,027	—	—
Liabilities:				
Contingent consideration	$ 3,105,225	—	—	$ 3,105,225

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the year ended December 31, 2019:

	Contingent Consideration
Balance at December 31, 2017	$ 2,609,289
Change in fair value	495,936
Balance at December 31, 2018	$ 3,105,225
Change in fair value	613,290
Balance at December 31, 2019	$ 3,718,515

The change in the fair value of the contingent consideration of $613,290 and $495,936 for the years ended December 31, 2019 and 2018 was primarily due to the effect of the change in discount rate, probability of achieving milestones, and passage of time on the fair value measurement. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statement of operations and comprehensive loss.

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The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements of contingent consideration classified as Level 3 as of December 31, 2019 and 2018:

	As of December 31, 2019		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Probability weighted income approach	Milestone dates	2020-2026
		Discount rate	7.83%
		Probability of occurrence	2.1% to 82%

	As of December 31, 2018		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Contingent Consideration	Probability weighted income approach	Milestone dates	2019-2025
		Discount rate	7.20%
		Probability of occurrence	1.6% to 62.5%

Income Tax

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

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2019 and 2018, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2019 and 2018, the Company had no such accruals.

On December 22, 2017, the Tax Cuts and Jobs Act ("Tax Act") was signed into law. The Tax Act lowered the Federal corporate tax rate from 34% to 21% and made numerous other tax law changes. The Company has measured deferred tax assets at the enacted tax rate expected to apply when these temporary differences are expected to be realized or settled. Under the guidance of SAB 118, the Company is required to recognize the effect of tax law changes in the period of enactment. Reasonable estimates were made based on the Company's analysis of the Tax Act. These provisional amounts were adjusted during 2018 when additional information was obtained with no material adjustments.

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Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employee directors using a fair value method that requires the recognition of compensation expense for costs related to all stock-based payments, including stock options and restricted stock units. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model. The fair value of restricted stock units is estimated based on the closing price of the Company's stock on the date of grant, and for the purposes of expense recognition, the total new number of shares expected to vest is adjusted for estimated forfeitures.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes-Merton option pricing model on the date of grant for stock options and are recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, forfeiture rates and expected term. The expected volatility rates are estimated based on the actual volatility of comparable public companies over the expected term. The expected term for the years ended December 31, 2019 and 2018 represents the average time that options are expected to be outstanding based on the average of the vesting term and the contractual term of the option. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Net loss attributable to non-controlling interests

Net loss attributable to non-controlling interests is the result of the Company's consolidation of subsidiaries of which it does not own 100%. In October 2018, the Company entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in the Company's subsidiaries, Heat I, Inc. and Pelican, a related party prior to acquisition, for 35,000 shares of the Company's common stock. The stock exchange resulted in the Company owning 100% of Heat I, Inc. and increasing its controlling ownership inPelican from 80% to 85%. The Company's net loss attributable to non-controlling interests relates to the 15% ownership of Pelican that Heat does not own as of December 31, 2019 and 2018.

Revenue Recognition

Effective January 1, 2019, the Company has adopted ASU No. 2018-08 , *Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made.* The Company's sole source of revenue is grant revenue related to the CPRIT contract, which is being accounted for under ASC 958 as a conditional non-exchange contribution.

The CPRIT grant covers the periods from June 1, 2017 through May 31, 2020, for a total grant award of up to $15.2 million. CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. The first tranche of funding of $1.8 million was received in May 2017, and a second tranche of funding of $6.5 million was received in October 2017, and the third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 million will be awarded after we have fulfilled every requirement of the grant and the grant has been approved to be finalized. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred. As of December 31, 2019, the deferred revenue balance was $3.4 million with $10.3 million recognized as revenue since contract inception.

Business Combinations

We account for acquisitions using the acquisition method of accounting, which requires that all identifiable assets acquired and liabilities assumed be recorded at their estimated fair values. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from acquired patented technology. Management's estimates of fair value are based upon assumptions believed to be reasonable, but are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Other estimates associated with the accounting for acquisitions may change as additional information becomes available regarding the assets acquired and liabilities assumed (see Note 4).

Goodwill and In-Process Research and Development

The Company classifies intangible assets into three categories: (1) intangible assets with definite lives subject to amortization, (2) intangible assets with indefinite lives not subject to amortization and (3) goodwill. The Company determines the useful lives of definite-lived intangible assets after considering specific facts and circumstances related to each intangible asset. Factors the Company considers when determining useful lives include the contractual term of any agreement related to the asset, the historical performance of the asset, and other economic facts; including competition and specific market conditions. Intangible assets that are deemed to have definite lives are amortized, primarily on a straight-line basis, over their estimated useful lives. Intangible assets that are deemed to have indefinite lives, including goodwill, are reviewed for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test for indefinite-lived intangibles, other than goodwill, consists of a comparison of the fair value of the intangible asset with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate a potential impairment exists, using a fair value-based test. Pursuant to ASU 2017-04, the Company must record a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value. See Note 7 regarding impairment at December 31, 2019.

In-process research and development, or IPR&D, assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that the Company acquires, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

Deferred Revenue

Deferred revenue is comprised of proceeds of $3.4 million received from CPRIT for which the costs have not been incurred or the conditions of the award have not been met and grant funds received from an economic development grant agreement with the City of San Antonio ("Economic Development Grant") that we entered into on November 1, 2017. Under the Economic Development Grant, we received $0.2 million in state enterprise fund grants for the purpose of defraying costs toward the purchase of laboratory equipment. As part of the agreement, we will provide the city of San Antonio with a purchase money security interest in the equipment to secure the repayment of grant funds should we fail to perform under the terms and conditions of the agreement. Our obligations under the agreement include meeting certain employment levels for a period of not less than seven years commencing on or before December 31, 2017 and establishing Pelican's corporate headquarters in San Antonio. The Economic Development Grant funds will be recognized as income upon the achievement of the performance criteria and determination that the cash is no longer refundable to the State of Texas.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations. The Company estimates the fair value of the contingent consideration as of the acquisition date using the estimated future cash outflows based on the probability of meeting future milestones. The milestone payments will be made upon the achievement of clinical and commercialization milestones as well as single low digit royalty payments and payments upon receipt of sublicensing income. Subsequent to the date of acquisition, the Company reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets (see Note 4).

Research and Development

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

Impact of Recently Issued Accounting Standards:

In November 2018, the FASB issued ASU 2018-18: *Collaborative Arrangements (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606. This ASU, in part, requires that certain transactions with collaboration partners be excluded from revenue recognized under Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company adopted this ASU in the first quarter of 2020 and there was no material effect on the recognition or measurement of revenue in the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07: *Compensation – Stock Compensation (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees, and as a result, the accounting for share-based payments to non-employees will be substantially aligned. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year, early adoption is permitted but no earlier than an entity's adoption date of Topic 606. The Company adopted this ASU in the first quarter of 2019 and there was no material effect on the Company's results of operations or cash flows.

In June 2018, the FASB issued ASU No. 2018-08, *Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*, which is intended to clarify and improve the scope and the accounting guidance for contributions received and contributions made. The amendments in ASU No. 2018-08 should assist entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transaction) within the scope of Topic 958, Not-for-Profit Entities, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. This amendment applies to all entities that make or receive grants or contributions. This ASU is effective for public companies serving as a resource recipient for fiscal years beginning after June 15, 2018, including interim periods within that fiscal year. The Company adopted this ASU in the first quarter of 2019 and there was no material effect on the recognition or measurement of revenue in the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842), which requires recognition of a right-of-use asset and liability for future lease payments for contracts that meet the definition of a lease and requires disclosure of certain information about leasing arrangements. Generally, a lease exists when a contract or part of a contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In determining whether a lease exists, the Company considers whether a contract provides it with both the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the identified asset. The Company adopted the standard on January 1, 2019 using the optional transition method and, as a result, did not recast prior period unaudited comparative financial statements. The Company has determined that its leases, consisting of leases for office and laboratory space without optional terms or variable components, are operating leases. Adoption of the new standard resulted in the recording of operating lease right-of-use assets and associated lease liabilities of $520,399 and $528,253, respectively, as of January 1, 2019 on the consolidated balance sheet with no cumulative impact to accumulated deficit and did not have a material impact on the Company's results of operations or cash flows.

3. ***Short-Term Investments***

Short-term investments consist of equity securities with a maturity of greater than three months when acquired. The Company holds its securities at fair value as of December 31, 2019 and 2018. Unrealized gains and losses on securities are reported in the statement of operation. Short-term investments at December 31, 2019 and 2018 consisted of mutual funds with fair values of $5.7 million and $5.6 million, respectively.

4. ***Acquisition of Pelican Therapeutics***

In 2017, the Company consummated the acquisition of 80% of the outstanding equity of Pelican, a related party, and Pelican became a majority owned subsidiary of the Company. During the quarter ended March 31, 2018, cash consideration of approximately $300,000 was distributed to the participating Pelican stockholders and the remainder of approximately $200,000 for certain Pelican liabilities not satisfied was recognized as other income in the statements of operations and comprehensive loss for the period. In October 2018, Heat entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in Heat's subsidiaries, Heat I, Inc. and Pelican. The stock exchange resulted in Heat increasing its controlling ownership in Pelican from 80% to 85%.

Under the agreement, the Company is also obligated to make future payments based on the achievement of certain clinical and commercialization milestones, as well as low single digit royalty payments and payments upon receipt of sublicensing income.

- $2.0 million upon Pelican's dosing of the first patient in its first Phase 1 trial for an oncology indication;
- $1.5 million upon Pelican's dosing of the first patient in its first Phase 2 trial for an oncology indication;
- $3.0 million upon successful outcome of the first Phase 2 trial for an oncology indication;
- $6.0 million upon Pelican's dosing of the first patient in its first Phase 3 trial for an oncology indication;
- $3.0 million upon Pelican's dosing of the first patient in its first Phase 3 trial for a non- oncology indication;
- $7.5 million upon successful outcome of the first Phase 3 trial for an oncology indication;
- $3.0 million upon successful outcome of the first Phase 3 trial for a non-oncology indication;
- $7.5 million upon acceptance of a Biologics License Application (BLA) submission for an oncology indication;
- $3.0 million upon acceptance of a BLA submission for a non-oncology indication;
- $7.5 million upon first product indication approval in the United States or Europe for an oncology indication;
- $3.0 million upon first product indication approval in the United States or Europe for a non-oncology indication.

The fair value of these future milestone payments is reflected in the contingent consideration account under current liabilities with the non-current portion under long term liabilities on the balance sheet. The estimated fair value of the contingent consideration was determined using a probability-weighted income approach, at a discount of 7.83% based on the median yield of publicly traded non-investment grade debt of companies in the pharmaceutical industry. As discussed in Note 2, the Company estimates the fair value of the contingent consideration on a quarterly basis.

Goodwill was calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from this acquisition related largely to synergies expected from combining the operations. The goodwill is not deductible for income tax purposes. In-process R&D assets are treated as indefinite-lived until the completion or abandonment of the associated R&D program, at which time the appropriate useful lives will be determined. The Company calculated the fair value of the non-controlling interest acquired in the acquisition as 20% of the equity interest of Pelican, adjusted for a minority interest discount.

As discussed in Note 10, in May 2016, Pelican was awarded a $15.2 million CPRIT Grant from CPRIT for development of Pelican's lead product candidate, PTX-35. The CPRIT Grant is expected to support Pelican in developing PTX-35 through a Phase 1 clinical trial designed to evaluate PTX-35 in combination with other immunotherapies.

5. *Prepaid Expenses and Other Current Assets*

Prepaid expenses and other current assets consist of the following at:

	December 31,	
	2019	2018
Prepaid manufacturing expense	148,156	559,110
Prepaid insurance	120,851	284,931
Other prepaid expenses and current assets	132,162	117,261
Other current assets	19,159	15
	$ 420,328	$ 961,317

6. *Property and Equipment*

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

Property and equipment consisted of the following at:

	December 31,	
	2019	2018
Lab equipment	$ 1,311,853	$ 1,218,532
Computers	53,065	9,445
Furniture and fixtures	50,453	38,589
Leasehold improvements	14,259	58,146
Total	1,429,630	1,324,712
Accumulated depreciation	(870,220)	(681,566)
Property and equipment, net	$ 559,410	$ 643,146

Depreciation expense totaled $227,296 and $237,318 for the years ended December 31, 2019 and 2018, respectively.

7. *Goodwill and In-process R&D*

Goodwill of $2.2 million and in-process R&D of $5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 4. The Company performs an annual impairment test at the reporting unit level. However, during the year ended December 31, 2019, the Company experienced a sustained decline in the quoted market price of the Company's common stock and as a result the Company determined that as of September 30, 2019 it was more likely than not that the

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carrying value of these acquired intangibles exceeded their estimated fair value. Accordingly, the Company performed an interim impairment analysis as of that date using the income approach. This analysis required significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital. Pursuant to ASU 2017-04, the Company recorded a goodwill impairment charge for the excess of the reporting unit's carrying value over its fair value. During the year ended December 31, 2019, goodwill with a total carrying value of $2.2 million was written down to $1.5 million and an impairment charge of $0.7 million was recorded. The Company determined that the fair value of the IPR&D was in excess of its carrying value as of December 31, 2019 and 2018 and therefore no impairment was recorded for the IPR&D.

The following table provides a rollforward of the Company's goodwill as of December 31, 2018 and 2019:

	Goodwill
Goodwill from acquisition of Pelican	$ 2,189,338
Balance at December 31, 2018	2,189,338
Goodwill impairment loss	(737,000)
Balance at December 31, 2019	$ 1,452,338

The following table provides a rollforward of the Company's in-process R&D as of December 31, 2018. There was no change in in-process R&D during 2019.

	In-process R&D
In-process R&D from acquisition of Pelican	$ 5,866,000
Balance at December 31, 2018	$ 5,866,000

8. *Accrued Expenses*

Accrued expenses consist of the following at:

	December 31, 2019	December 31, 2018
Accrued clinical trial expenses	$ 1,156,618	$ 919,750
Compensation and related benefits	303,870	628,147
Patent fees	—	40,000
Deferred rent	—	7,854
Other expenses	215,979	82,300
	$ 1,676,467	$ 1,678,051

9. *License Agreements*

- *University of Miami*

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

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

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

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

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

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

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

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

- *University of Miami - Pelican*

For each agreement, the Company agreed to make minimum royalty payments of $10,000 for three years beginning 2010 due on the anniversary date of the agreements to the University of Miami. Beginning in 2013, and thereafter for the life of the agreements, the minimum royalty payments shall be $20,000 due on the same date.

License 0331, 0539:

- Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $250,000 due upon the earlier of May 2022 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

- In August 2009, Pelican and UM entered into a second amendment ("Amendment 2") to License Agreement 0331, 0539 to extend the foregoing payment due dates for all past due license fees and patent costs.

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- In February 2010, Pelican and UM entered into a third amendment ("Amendment 3") to License Agreement 0331, 0539 to grant back to UM a certain nonexclusive license. In all other respects, the original agreement remained the same.

- In October 2010, Pelican and UM entered into a fourth amendment ("Amendment 4") to License Agreement 0331, 0539 to grant to the licensor a nonexclusive license right for certain technology as research reagents and research tools.

License I176:

- On December 12, 2010, Pelican entered into another license agreement ("I176") with UM for one component of complimentary technology to the July 11, 2008 agreement. Pelican agreed to pay UM a license fee of $50,000 and a reimbursement of $15,797 for past patent fees. Pelican also agreed to make a minimum royalty payment of $10,000 during 2012 through 2014 and then $20,000 every year thereafter. Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $500,000 due upon the earlier of May 2022 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

- In August 2012, Pelican and UM entered into a second amendment ("I176 Amendment 2") to License Agreement I176 to extend the foregoing payment due dates for all past due license fees and patent costs.

UMM143:

- On November 19, 2013, Pelican entered into another license agreement ("UMM143") with UM for an exclusive license of complimentary technology and patent rights. Pelican agreed to pay UM a license issue fee of $35,000 and agreed to make minimum royalty payments if the I176 license agreement is terminated. No minimum royalty payments or milestone payments are due for any year in which the I176 license agreement is in force. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

- *Other License Agreements*

- On April 12, 2011, the Company entered into a non-exclusive evaluation and biological material license agreement with a not-for-profit corporation for evaluation and production of vaccines. In consideration for the evaluation and commercial use license, the Company agreed to pay the not-for-profit corporation a fee of $5,000 and $50,000, respectively. The Company has the option to renew the license once the original term has expired. Milestone payments are due upon certain events agreed upon by Heat and the not-for-profit corporation. In December 2015, the Company amended the evaluation and biological material license agreement to add additional cell lines in exchange for a one-time payment of $1,000.

- On August 30, 2010, the Company entered into an option agreement with the University of Michigan ("University") to acquire the right to negotiate an exclusive license for certain materials which include cancer cells and all unmodified derivatives of these cells. An option fee of $2,000 was paid on September 8, 2010 to grant a period of nine months for this consideration. In July 2011, the Company exercised the option to acquire the license for $10,000.

- In June 2016, the Company entered into an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which the Company licensed certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by us. Shattuck paid the Company an initial license fee of $50,000 and is obligated to pay the Company fees upon its receipt of sublicensing income, achievement of certain milestones and royalties upon sales of commercial products.

Inasmuch as the technology that the Company out-licensed is in the early stages of development and there is a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that the Company will derive any revenue from Shattuck.

Future minimum royalty payments by the Company for licenses as of December 31, 2019 are as follows (in thousands):

Year ended December 31,	
2020	$ 103
2021	228
2022	784
2023	74
2024	—
Total	$ 1,189

10. Grant Revenue

In June 2016, Pelican entered into a cancer research grant contract or Grant Contract with CPRIT, under which CPRIT awarded a grant not to exceed $15.2 million for use in developing cancer treatments by targeting a novel T-cell costimulatory receptor (namely, TNFRSF25). The Grant Contract initially covered a period from June 1, 2016 through November 30, 2019, as amended, was extended to May 30, 2020. The first tranche of funding of $1.8 million was received in May 2017, a second tranche of funding of $6.5 million was received in October 2017, and a third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 will be awarded after we have fulfilled every requirement of the grant and the grant has been approved to be finalized.

The grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT. Consequently, Pelican is required to provide $7.6 million in matching funds over the life of the project. Upon commercialization of the product, the terms of the grant require Pelican to pay tiered royalties in the low to mid-single digit percentages. Such royalties reduce to less than one percent after a mid-single-digit multiple of the grant funds have been paid to CPRIT in royalties.

Through December 31, 2019, $10.3 million of grant funding received to date has been recognized as revenue.

11. Stockholders' Equity

Authorized Capital

Heat has authorized 10,000,000 shares of Preferred Stock (par value $0.0001) as of December 31, 2019 and 2018. As of December 31, 2019 and 2018, there were no outstanding shares of Preferred Stock.

Heat had 100,000,000 shares of common stock (par value $0.0002) authorized as of December 31, 2019 and 2018. On March 20, 2020, an amendment to increase the authorized shares of common stock to 250,000,000 was filed. As of December 31, 2019, and 2018, 33,785,999 and 32,492,144 common stock shares were issued and outstanding as of December 31, 2019 and 2018, respectively.

Financings

On January 18, 2018, the Company entered into a Common Stock Sales Agreement (the "Underwriting Agreement") with H.C. Wainwright & Co., LLC, ("HCW") as sales agent, pursuant to which the Company may sell from time to time, at its option, shares of its common stock, for the sale of up to $3.7 million of shares of the Company's common stock and on March 15, 2018 filed with the SEC a prospectus supplement for an additional aggregate offering of up to $1.3 million shares of Common Stock. Sales of shares of Common Stock have been made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-221201) filed with the U.S. Securities and Exchange Commission ("SEC"), dated November 13, 2017 ("2017 Shelf"). As of December 31, 2018, the Company sold an aggregate of 1,566,997 shares of common stock under the HCW Sales Agreement resulting in net proceeds of approximately \$3.8 million.

On May 7, 2018, the Company closed an underwritten public offering (the "Offering") in which it issued and sold (i) 4,875,000 shares of common stock together with a number of common warrants to purchase 2,437,500 shares of its common stock, and (ii) 9,500,000 pre-funded warrants, with each pre-funded warrant exercisable for one share of common stock, together with a number of common warrants to purchase 4,750,000 shares of its common stock. The public offering price was \$1.44 per share of common stock, \$1.43 per pre-funded warrant and \$0.01 per common warrant. The net proceeds to the Company were approximately \$18.8 million, net of underwriting discounts and commissions and other estimated offering expenses. The common stock warrants expire five years after date of issuance and have an exercise price of \$1.584 per share. As of December 31, 2018, 3,054,667 common stock warrants have been exercised for an additional \$4.8 million of proceeds to the Company and all pre-funded warrants have been exercised. In connection with the offering the Company entered into an underwriting agreement, dated May 2, 2018 with A.G.P./Alliance Global Partners (A.G.P.), as representative of the underwriters. The Underwriting Agreement contained customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the "Securities Act"), other obligations of the parties and termination provisions.

On November 26, 2018, the Company closed an underwritten public offering in which it issued and sold 8,000,000 shares of the Company's common stock together with warrants to purchase 4,000,000 shares of the Company's common stock at a combined price to the public of \$1.50. The warrants have an exercise price of \$1.65, are exercisable upon issuance and expire five years from the date of issuance. In addition, the underwriter exercised the over-allotment option to purchase an additional 1,200,000 shares of common stock and warrants to purchase 600,000 shares of common stock. Net proceeds to Heat from this offering are approximately \$12.7 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by Heat. A.G.P./Alliance Global Partners acted as the sole book-running manager for the offering.

Common Stock Warrants

In connection with the November 26, 2018 public offering, the Company issued 4,600,000 common stock warrants of which are exercisable for one share of common stock. The common stock warrants have an exercise price of \$1.65 per share and expire five years from the issuance date. The warrants have been accounted for as equity instruments. The fair value of the common stock warrants of approximately \$5.6 million at the date of issuance was estimated using the Black-Scholes Merton model which used the following inputs: term of 5 years, risk free rate of 2.89%, 0% dividend yield, volatility of 133.26%, and share price of \$1.42 per share based on the trading price of the Company's common stock.

In connection with the May 7, 2018 public offering, the Company issued 9,500,000 pre-funded warrants and 7,187,500 common stock warrants each of which are exercisable for one share of common stock. The pre-funded warrants had an exercise price of \$0.01 per share and as of December 31, 2019 all pre-funded warrants have been exercised. The common stock warrants have an exercise price of \$1.584 per share and expire five years from the issuance date. As of December 31, 2019, 3,054,667 common stock warrants have been exercised. The warrants have been accounted for as equity instruments. The fair value of the common stock warrants of approximately \$7.8 million at the date of issuance was estimated using the Black-Scholes Merton model which used the following inputs: term of 5 years, risk free rate of 2.78%, 0% dividend yield, volatility of 124.14%, and share price of \$1.30 per share based on the trading price of the Company's common stock.

In connection with the March 23, 2016 public offering, the Company issued warrants to purchase 682,500 shares of common stock with an exercise price of \$10.00 per share that expire five years from the issuance date. In connection with the Company's July 23, 2013 initial public offering, the Company issued warrants to the underwriters for 12,500 shares of common stock issuable at \$125.00 per share which expired July 22, 2018. On March 10, 2011, the Company issued warrants to purchase shares of common stock to third parties in consideration for a private equity placement transaction of which 1,738 warrants remain outstanding. The warrants have an exercise price of $4.80 per share and expire ten years from the issuance date.

During the year ended December 31, 2018, 3,054,667 common stock warrants have been exercised and 12,500 common stock warrants have expired. No warrants were issued or exercised during the same period in 2019. As of December 31, 2019 the Company has outstanding warrants to purchase 4,600,000 shares of common stock issuable at $1.65 per share, 4,132,833 shares of common stock issuable at $1.584 per share, 296,159 shares of common stock issuable at $10.00 per share; and warrants to purchase 1,738 shares of common stock issuable at $4.80 per share. These warrants do not meet the criteria required to be classified as liability awards and therefore are treated as equity awards.

The Company has a total of 9,030,730 warrants outstanding at a weighted average exercise price of $1.89 to purchase its common stock as of December 31, 2019. These warrants are summarized as follows:

Issuance Date	Number of Shares	Exercise Price	Expiration Date
3/10/2011	1,738	$ 4.80	3/10/2021
3/23/2016	296,159	$ 10.00	3/23/2021
5/7/2018	4,132,833	$ 1.58	5/8/2023
11/26/2018	4,600,000	$ 1.65	11/26/2023

The following table summarizes the warrant activity of the Company's common stock warrants. There were no changes in the Company's outstanding warrants during 2019:

	Common Stock Warrants
Outstanding, December 31, 2017	310,397
Issued	11,787,500
Exercised	(3,054,667)
Expired	(12,500)
Outstanding, December 31, 2018	9,030,730

Equity Compensation Plans

2009 Stock Incentive Plan

In 2009, the Company adopted the 2009 Stock Option Plan of Heat Biologics, Inc. (the "2009 Plan"), under which stock options to acquire 21,739 common shares could be granted to key employees, directors, and independent contractors. Under the 2009 Plan, both incentive and non-qualified stock options could be granted under terms and conditions established by the Board of Directors. The exercise price for incentive stock options was the fair market value of the related common stock on the date the stock option was granted. Stock options granted under the 2009 Plan generally have terms of 10 years and have various vesting schedules.

The Company amended the 2009 Stock Option Plan and all related addendum agreements in April 2011. This second amendment increased the number of shares available for issuance from 21,739 to 65,217. The Company amended the 2009 Plan to increase the number of shares available for issuance to 86,957. The 2009 Plan expired in September 2019, however all options outstanding at the time of expiration remained outstanding and exercisable by their term. As of December 31, 2019 and 2018, there were 47,267 and 23,799 stock options outstanding under the 2009 Plan, respectively.

2014 Stock Incentive Plan

In June 2014, the stockholders approved the 2014 Stock Option Plan of Heat Biologics, Inc. (the "2014 Plan"), under which the Company is authorized to grant 50,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock based awards with terms established by the Compensation

Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2014 Plan. In 2015, the stockholders approved an amendment to the Plan to increase the number of shares by 60,000 and in 2016, the stockholders approved an amendment that allowed the Company to grant up to 300,000 awards in total. As of December 31, 2019 and 2018, there were 228,276 and 263,484 stock options outstanding under the 2014 Plan, respectively.

2017 Stock Incentive Plan

In June 2017, the stockholders approved the 2017 Stock Incentive Plan of Heat Biologics, Inc. (the "2017 Plan"), under which the Company is authorized to grant 500,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2017 Plan. As of December 31, 2019 and 2018 there were 345,383 and 234,540 stock options outstanding under the 2017 Plan, respectively.

2018 Stock Incentive Plan

In October 2018, the stockholders approved the 2018 Stock Incentive Plan of Heat Biologics, Inc. (the "2018 Plan"), under which the Company is authorized to grant 4,000,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2018 Plan. At our 2019 Annual Meeting of Stockholders, the stockholders approved an amendment to the Plan to increase the number of shares by 4,000,000. As of December 31, 2019 and 2018 there were 3,729,264 and nil stock options outstanding under the 2018 plan, respectively.

There are 3,219,346 stock options remaining available for grant under the Plans. The following table summarizes the components of the Company's stock-based compensation included in net loss:

	For the years ended December 31, 2019	2018
Employee stock options	$ 1,349,089	$ 443,684
Non-employee stock options	351,812	20,420
Employee stock awards	1,243,526	318,186
Non-employee stock awards	325,521	6,369
	$ 3,269,948	$ 788,659

Accounting for Stock-Based Compensation:

Stock Compensation Expense - For the years ended December 31, 2019, and 2018, we recorded $3,269,948, and $788,659 of stock-based compensation expense, respectively. No compensation expense of employees with stock awards was capitalized during the years ended December 31, 2019 and 2018.

Stock Options - Under the Plan, we have issued stock options. A stock option granted gives the holder the right, but not the obligation to purchase a certain number of shares at a predetermined price for a specific period of time. We typically issue options that vest over four years in equal installments beginning on the first anniversary of the date of grant. Under the terms of the Plan, the contractual life of the option grants may not exceed ten years. During the years ended December 31, 2019, and 2018, we issued options that expire ten years from the date of grant.

Fair Value Determination - We have used the Black-Scholes-Merton option pricing model to determine fair value of our stock option awards on the date of grant. We will reconsider the use of the Black-Scholes-Merton model if additional information becomes available in the future that indicates another model would be more appropriate or if grants issued in future periods have characteristics that cannot be reasonably estimated under this model.

The following weighted-average assumptions were used for option grants during the years ended December 31, 2019 and 2018:

- ***Volatility*** – The Company used an average historical stock price volatility based on an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms, as the Company had a limited to no trading history for its common stock.

- ***Expected life of options*** – The expected term represents the period that the Company's stock option grants are expected to be outstanding. The Company elected to utilize the "simplified" method to estimate the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

- ***Risk-free interest rate*** – The rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options.

- ***Dividend yield*** – The expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plan to do so in the future.

- ***Forfeitures*** – As required by ASC 718, the Company reviews recent forfeitures and stock compensation expense. Forfeitures are estimated at the time of the grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Additionally, the Company conducts a sensitivity analysis of the forfeiture rate. Based on these evaluations the Company currently does not apply a forfeiture rate.

The following table summarizes weighted-average assumptions used in our calculations of fair value for the years ended December 31, 2019 and 2018:

	December 31,	
	2019	2018
Dividend yield	— %	— %
Expected volatility	89.59-91.03 %	83.63-121.81 %
Risk-free interest rate	1.63-2.52 %	2.32-2.98 %
Expected lives (years)	5.4-6.3	5.1-6.3

Stock Option Activity - The weighted-average fair value of options granted during the years ended December 31, 2019 and 2018, as determined under the Black-Scholes valuation model, was $0.75 and $2.65, respectively.

The following table summarizes stock option activity for the years ended December 31, 2019 and 2018:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2017	266,810	$ 19.57	
Granted	221,410	3.57	
Cancelled and expired	(22,917)	26.97	
Stock options outstanding at December 31, 2018	465,303	11.60	
Granted	2,920,021	1.03	
Exercised	(2,000)	1.06	
Forfeited/Expired	(319,688)	1.76	
Stock options outstanding at December 31, 2019	3,063,636	$ 2.56	8.57 Years
Stock options exercisable at December 31, 2019	1,337,600	$ 4.21	8.23 Years

Unrecognized compensation expense related to unvested stock options was $1.0 million as of December 31, 2019, which is expected to be recognized over a weighted-average period of 1.3 years and will be adjusted for forfeitures as they occur.

Restricted Stock - Under the Plan, we have issued restricted stock. A restricted stock award is an issuance of shares that cannot be sold or transferred by the recipient until the vesting period lapses. Restricted stock issued to members of our Board of Directors and Executives vest 50% on grant date, 30% on the first anniversary and 10% each anniversary thereafter. The grant date fair value of the restricted stock is equal to the closing market price of our common stock on the date of grant.

Restricted Stock Activity - The following table summarizes the restricted stock activity during the years ended December 31, 2019 and 2018:

	Shares	Weighted Average Fair Value
Restricted stock at December 31, 2018	—	$ —
Granted	2,479,179	0.85
Vested	(1,179,811)	0.84
Cancelled	(44,715)	1.06
Restricted stock at December 31, 2019	1,254,653	$ 0.86

RSUs - Under the Plan, we issued time-based RSUs. RSUs are not actual shares, but rather a right to receive shares in the future. The shares are not issued and the employee cannot sell or transfer shares prior to vesting and has no voting rights until the RSUs vest. The employees' time-based RSUs will result in the delivery of shares in one-fourth increments commencing on the award date. The grant date fair value of the RSUs is equal to the closing market price of our common stock on the grant date. We recognize the grant date fair value of RSUs of shares we expect to issue as compensation expense ratably over the requisite service period.

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following table summarizes the RSU activity during the years ended December 31, 2019 and 2018:

	Shares	Weighted Average Fair Value
RSUs at December 31, 2017	21,826	$ 8.68
Granted	99,614	3.97
Vested	(59,794)	4.59
Cancelled	(5,126)	5.93
RSUs at December 31, 2018	56,520	$ 4.95
Vested	(21,744)	5.34
Cancelled	(4,750)	5.63
RSUs at December 31, 2019	30,026	$ 4.33

12. Income Tax

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

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2019 and 2018, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations. As of December 31, 2019 and 2018, the Company had no such accruals.

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

	2019	2018
Current Expense:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	—	—
Deferred Expense:		
Federal	$ 45,178	$ (985,488)
State	—	—
Foreign	—	—
Total	$ 45,178	$ (985,488)

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The differences between the company's income tax expense attributable to continuing operations and the expense computed at the 21 % United States statutory income tax rate were as follows:

	2019	2018
Federal income tax expense at statutory rate:	$ (4,271,000)	$ (3,577,000)
Increase (reduction) in income tax resulting from:		
State Income Taxes	(581,000)	(207,000)
Foreign Rate Differential	(9,000)	(17,000)
Nondeductible Expenses	15,000	7,000
Prior Period True-Up - Pelican	—	208,000
Research & Development Credit	(772,000)	(763,000)
Stock Based Compensation	132,000	60,000
Excess Executive Compensation	295,000	—
Goodwill Impairment	155,000	
Reserve for Loss Carryforwards Limited by Sec. 382	8,000	22,000
Other	74,178	25,512
Increase in Valuation Allowance	4,999,000	3,256,000
	$ 45,178	$ (985,488)

The tax effects of temporary differences and operating loss carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities were as follows at December 31, 2019 and December 31, 2018:

	2019	2018
Deferred tax assets:		
Net Operating Loss Carryforward	$ 22,278,013	$ 18,731,555
R&D Credits	3,829,550	2,729,737
Stock Compensation	878,094	744,506
Contingent Consideration	854,129	713,259
Lease Liability	9,950	—
Other Accrued Expenses	20,797	—
Deferred tax assets	27,870,533	22,919,057
Deferred tax liabilities:		
Property, plant and equipment, primarily due to differences in depreciation	(91,764)	(127,140)
Other Accrued Expenses	—	(11,926)
Intangible Assets	(1,347,399)	(1,302,220)
Deferred tax liabilities	(1,439,163)	(1,441,286)
Valuation allowance	(26,793,281)	(21,794,504)
Net deferred tax assets (liabilities)	$ (361,911)	$ (316,733)

At December 31, 2019 and December 31, 2018, the Company evaluated all significant available positive and negative evidence, including the existence of losses in recent years and management's forecast of future taxable income, and, as a result, determined it was more likely than not that federal and state deferred tax assets, including benefits related to net operating loss carryforwards, would not be realized. The valuation allowance was increased from $21,794,504 at December 31, 2018 to $26,793,281 at December 31, 2019. Net Operating Losses created in years beginning after 2017 now only offset 80% of Taxable Income but no longer have a 20 year expiration. As such, NOL's created after 2018 can be used to offset indefinite lived liabilities up to 80%.

At December 31, 2019, the Company has federal net operating loss carryforwards of approximately $100,199,714, including $3,027,284 acquired from Pelican Therapeutics, which are available to offset future taxable income. However, due to potential Section 382 limitations (discussed in further detail below) a reserve has been set up for the Pelican Therapeutics NOL of $(2,380,864). The federal net operating loss carryforwards begin to expire in 2029. The Company has various state net operating loss carryforwards totaling approximately $87,841,606 including $2,464,819 from Pelican Therapeutics, which are available to offset future state taxable income. State net operating losses begin to expire in 2024. The Company has various foreign net operating loss carryforwards of approximately $96,032. The foreign net operating loss carryforwards are carried forward indefinitely. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, state, and foreign income tax authorities.

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered ‘more-likely-than-not’ that the position taken will be sustained by a taxing authority. As of December 31, 2019, and 2018, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company’s effective income tax rate associated with these items. The Company’s policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of income. As of December 31, 2019, and 2018, the Company had no such accruals.

The Company files income tax returns in the United States, various state and foreign jurisdictions. The Company is subject to examination by taxing authorities for the tax years ended December 31, 2009 through 2018.

Potential 382 Limitation

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

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

13. Leases

As described in Note 2, effective January 1, 2019, the Company adopted ASC 842 using the optional transition method, applying no practical expedients. In accordance with the optional transition method, the Company did not recast the prior period consolidated financial statements. The lease term is the noncancelable period of the lease. There are no termination provisions or renewal periods reasonably certain of exercise or options controlled by the lessor.

The Company conducts its operations from leased facilities in Morrisville, North Carolina, and San Antonio, Texas, the leases for which will expire in 2027 and 2023. The leases are for general office space and require the Company to pay property taxes, insurance, common area expenses and maintenance costs.

HEAT BIOLOGICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

On October 1, 2019, commencement date of our Morrisville, North Carolina lease, a right-of-use asset of $2.0 million and a liability of $1.4 million were recorded on our balance sheet. Total cash paid for operating leases during the year ended December 31, 2019 was $0.7 million and is included within cash flows from operating activities within the consolidated statement of cash flows.

The Company leases furniture and specialized lab equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. The effective interest rate is 6.2%.

The Company's lease cost reflected in the accompanying Statements of Operations and Comprehensive loss as follows:

	For the Year Ended December 31, 2019
Operating lease cost	$ 191,737
Finance lease cost	
Amortization of lease assets	5,210
Interest on lease liabilities	954
Lease cost	$ 6,164

The weighted average remaining lease term and incremental borrowing rate as of December 31, 2019 were as follows:

Weighted average remaining lease term (years)	
Operating leases	7 years
Finance leases	3 years
Weighted average discount rate	
Operating leases	6.58 %
Finance leases	6.17 %

Maturities of operating and finance lease liabilities as of December 31, 2019 were as follows:

For the year ending December 31:	Operating Leases	Finance Leases	Total
2020	$ 321,273	58,980	380,253
2021	330,032	58,980	389,012
2022	338,960	93,990	432,950
2023	244,973	-	244,973
2024	231,503	-	231,503
Thereafter	693,272	-	693,272
Total minimum lease payments	2,160,013	211,950	2,371,963
Less: Interest	(423,607)	(20,179)	(443,786)
Present value of lease liabilities	$ 1,736,406	191,771	1,928,177

Maturities of operating lease liabilities as of December 31, 2018 were as follows:

For the year ending December 31:		
2019		309,729
2020		115,580
2021		118,158
2022		120,736
2023		20,194
Total	$	684,397

14. Non-Controlling Interest

In October 2018, Heat entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in Heat's subsidiaries, Heat I, Inc. and Pelican Therapeutics, Inc. ("Pelican"), a related party prior to acquisition. The stock exchangeresulted in Heat owning 100% of Heat I, Inc. and increasing its controlling ownership in Pelican from 80% to 85%.

15. Related Party Transactions

The Company compensates its board members. Board members received cash compensation between approximately $61,500 and $221,000, for services rendered during 2019 and 2018, respectively. Board members also received equity compensation.

The Company owns 85% of the outstanding equity of Pelican, a related party as of the year ended December 31, 2019. See Note 4 about future milestone payments that may be paid to Participating Pelican Shareholders.

16. Net Loss Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the periods. Fully diluted net loss per common share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. Common equivalent shares consist of stock options and warrants that are computed using the treasury stock method.

For the years ended December 31, 2019 and 2018, all of the Company's common stock options, unvested restricted stock units and warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

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

	For the years ended December 31,	
	2019	**2018**
Net loss	$ (20,384,716)	$ (16,591,293)
Net loss - Non-controlling interest	(367,148)	(857,439)
Net loss attributable to Heat Biologics, Inc.	$ (20,017,568)	$ (15,733,854)
Weighted-average number of common shares used in net loss per share attributable to common stockholders —basic and diluted	33,281,817	17,485,461
Net loss per share attributable to Heat Biologics, Inc —basic and diluted	$ (0.60)	$ (0.90)

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

	For the years ended December 31,	
	2019	2018
Outstanding stock options	3,063,636	465,303
Restricted stock subject to forfeiture and restricted stock units	1,284,679	56,520
Outstanding common stock warrants	9,030,730	9,030,730

17. Subsequent Events

On January 21, 2020, we closed on a public offering consisting of 20,000,000 shares of common stock together with Warrants to purchase 10,000,000 shares of common stock. The gross proceeds to the Company from this offering were approximately $7,000,000, before deducting underwriting discounts, commissions and other offering expenses. As of March 3, 2020, investors exercised 9,960,000 warrants through a cashless exercise for 7,470,000 shares of common stock.

Between March 2, 2020 and March 3, 2020, the Company entered into exchange agreements with holders of its warrants issued in 2018 extinguishing 3,291,666 shares of its common stock through the issuance of 2,238,332 shares of common stock.

On March 12, 2020, the Company filed a Form S-8 Registration Statement with the Securities and Exchange Commission for an aggregate of 12,000,000 shares of the Company's common stock, $0.001 par value per share, that are subject to issuance by the Company under the Company's 2018 Stock Incentive Plan.

Subsequent to the year ended December 31, 2019, the Company has issued an additional 12,051,735 shares of common stock in "at-the-market" offerings under the 2017 Shelf and received $10.8 million of net proceeds.

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. A health pandemic is a disease outbreak that spreads rapidly and widely by infection and affects many individuals in an area or population at the same time. Heat and the business of the supplier of our clinical product candidate and the suppliers of the standard of care drugs that are administered in combination with our clinical product candidate could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis. Such events could result in the complete or partial closure of one or more manufacturing facilities which could impact our supply of our clinical product candidate or the standard of care drugs that are administered in combination with our clinical product candidate. In addition, an outbreak near our clinical trial sites are located would likely impact our ability to recruit patients, delay our clinical trials, and could affect our ability to complete our clinical trials within the planned time periods. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships. It is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on our business or results of operations at this time.

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

As of December 31, 2019, Heat Biologics, Inc. (the "Company," "we," "us," and "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is our common stock, par value $0.0002 per share (the "common stock").

General

The following is a description of the material terms of our common stock. This is a summary only and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Third Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation"), and our Amended and Restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31. 2019, of which this Exhibit 4.20 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law, for additional information.

Description of Common Stock

Authorized Shares of Common Stock. We currently have authorized 100,000,000 shares of common stock. As of March 23, 2020, we had 79,384,021 issued and outstanding shares of common stock.

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences. The holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our issued and outstanding shares of common stock are fully paid and nonassessable.

Stockholder Rights Plan

On March 11, 2018, our board of directors declared a dividend of one Right for each outstanding share of our common stock, which was amended by Amendment No. 1 thereto on March 8, 2019 and by Amendment No. 2 thereto on March 10, 2020 to extend the expiration date of the stockholder's rights plan to March 11, 2021. The dividend was initially paid on March 23, 2018 (the "Record Date") to the stockholders of record at the close of business on that date. Each Right initially entitles the registered holder to purchase from us one share of common stock at a price of $14.00 per share of common stock (the "Purchase Price"), subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement, dated as of March 11, 2018, as amended by Amendment No. 1 thereto dated March 8, 2019 and Amendment No. 2 thereto dated March 10, 2020, as the same may be further amended from time to time (the "Rights Agreement"), between the Company and Continental Stock Transfer & Trust Company, as Rights Agent (the "Rights Agent").

The Rights are designed to assure that all of our stockholders receive fair and equal treatment in the event of a hostile takeover of the Company, to guard against two-tier or partial tender offers, open market accumulations and other tactics designed to gain control of the Company without paying all stockholders a fair price, and to enhance the board of director's ability to negotiate with any prospective acquiror. Until the earlier to occur of (i) 10 business days following a public announcement that a person or group of affiliated or associated persons has become an Acquiring Person (as defined below) or (ii) 10 business days (or such later date as may be determined by action of the board of directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) following the commencement of, or public announcement of an intention to make, a tender or exchange offer the consummation of which would result in any person or group of affiliated or associated persons becoming an Acquiring Person (the earlier of such dates being called the "Distribution Date"), the Rights will be evidenced, with respect to certificates representing common stock (or book entry shares of common stock) outstanding as of the Record Date, by such certificates (or such book entry shares) together with a copy of a summary of the Rights (the "Summary of Rights"). Except in certain situations, a person or group of affiliated or associated persons becomes an "Acquiring Person" upon acquiring beneficial ownership of 20% or more of the outstanding shares of common stock. Certain synthetic interests in securities created by derivative positions – whether or not such interests are considered to be ownership of the underlying common stock or are reportable for purposes of Regulation 13D of the Exchange Act – are treated as beneficial ownership of the number of shares of the common stock equivalent to the economic exposure created by the derivative security, to the extent actual shares of common stock are directly or indirectly beneficially owned by a counterparty to such derivative security.

The Rights Agreement provides that, until the Distribution Date (or earlier expiration of the Rights), the Rights will be transferred with and only with the common stock. Until the Distribution Date (or earlier expiration of the Rights), new common stock certificates issued after the Record Date upon transfer or new issuances of common stock will contain a notation incorporating the Rights Agreement by reference. Until the Distribution Date (or earlier expiration of the Rights), the surrender for transfer of any certificates for shares of common stock (or book entry shares of common stock) outstanding as of the Record Date, even without such notation or a copy of the Summary of Rights, will also constitute the transfer of the Rights associated with the shares of common stock represented thereby. As soon as practicable following the Distribution Date, separate certificates evidencing the Rights ("Right Certificates") will be mailed to holders of record of the common stock as of the close of business on the Distribution Date and such separate Right Certificates alone will evidence the Rights.

The Rights are not exercisable until the Distribution Date. The Rights will expire at the close of business on March 11, 2021, unless the Rights are earlier redeemed or exchanged by the Company as described below.

The Purchase Price payable, and the number of shares of common stock (or cash, other assets, debt securities of the Company, or any combination thereof equivalent in value thereto) issuable, upon exercise of the Rights is subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of, the common stock, (ii) upon the grant to holders of the common stock of certain rights or warrants to subscribe for or purchase common stock at a price, or securities convertible into common stock with a conversion price, less than the then-current market price of the common stock or (iii) upon the distribution to holders of the common stock of evidences of indebtedness or assets (excluding regular periodic cash dividends or dividends payable in common stock) or of subscription rights or warrants (other than those referred to above).

The number of outstanding Rights is subject to adjustment in the event of a stock dividend on the common stock payable in shares of common stock or subdivisions, consolidations or combinations of the common stock occurring, in any such case, prior to the Distribution Date.

In the event that any person or group of affiliated or associated persons becomes an Acquiring Person, each holder of a Right, other than Rights beneficially owned by the Acquiring Person (which will thereupon become void), will thereafter have the right to receive upon exercise of a Right that number of shares of common stock (or cash, property debt securities of the Company, or any combination thereof) having a market value of two times the exercise price of the Right.

In the event that, after a person or group has become an Acquiring Person, the Company is acquired in a merger or other business combination transaction or 50% or more of its consolidated assets or earning power are sold, proper provisions will be made so that each holder of a Right (other than Rights beneficially owned by an Acquiring Person which will have become void) will thereafter have the right to receive upon the exercise of a Right that number of shares of common stock of the person with whom the Company has engaged in the foregoing transaction (or its parent) that at the time of such transaction have a market value of two times the exercise price of the Right.

At any time after any person or group becomes an Acquiring Person and prior to the earlier of one of the events described in the previous paragraph or the acquisition by such Acquiring Person of 50% or more of the outstanding shares of common stock, the board of directors may exchange the Rights (other than Rights owned by such Acquiring Person which will have become void), in whole or in part, for shares of common stock (or cash, other assets, debt securities of the Company, or any combination thereof with an aggregate value equal to such shares) at an exchange ratio of one share of common stock (or cash, other assets, debt securities of the Company, or any combination thereof equivalent in value thereto) per Right.

With certain exceptions, no adjustment in the Purchase Price will be required until cumulative adjustments require an adjustment of at least 1% in such Purchase Price. No fractional shares of common stock will be issued, and in lieu thereof a cash payment will be made based on then current market price of the common stock.

At any time prior to the time an Acquiring Person becomes such, the Board may redeem the Rights in whole, but not in part, at a price of $0.001 per Right (the "Redemption Price") payable, at the option of the Company, in cash, shares of common stock or such other form of consideration as the board of directors shall determine. The redemption of the Rights may be made effective at such time, on such basis and with such conditions as the board of directors in its sole discretion may establish. Immediately upon any redemption of the Rights, the right to exercise the Rights will terminate and the only right of the holders of Rights will be to receive the Redemption Price.

For so long as the Rights are then redeemable, the Company may, except with respect to the Redemption Price, amend the Rights Agreement in any manner. After the Rights are no longer redeemable, the Company may, except with respect to the Redemption Price, amend the Rights Agreement in any manner that does not adversely affect the interests of holders of the Rights.

Until a Right is exercised or exchanged, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends. For more detailed information, please see the Rights Agreement.

Potential Anti-Takeover Effects

Certain provisions set forth in our Certificate of Incorporation and Bylaws, our Rights Agreement and in Delaware law, which are summarized below, may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders.

Proposals of business and nominations. Our Bylaws generally regulate proposals of business and nominations for election of directors by stockholders. In general, Section 2.14 requires stockholders intending to submit proposals or nominations at a stockholders meeting to provide the Company with advance notice thereof, including information regarding the stockholder proposing the business or nomination as well as information regarding the proposed business or nominee. Section 2.13 provides a time period during which business or nominations must be provided to the Company that will create a predictable window for the submission of such notices, eliminating the risk that the Company finds a meeting will be contested after printing its proxy materials for an uncontested election and providing the Company with a reasonable opportunity to respond to nominations and proposals by stockholders.

Board Vacancies. Our Bylaws generally provide that only the board of directors (and not the stockholders) may fill vacancies and newly created directorships.

Special Meeting of Stockholders. Our Bylaws generally provide that only the board of directors (and no other third party) may call a special meeting of stockholders and that the board of directors may postpone, reschedule or cancel any special meeting of stockholders that was previously scheduled by the board of directors.

Stockholder Rights Plan. The rights issued pursuant to the Rights Agreement, if not redeemed or suspended, could work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

While the foregoing provisions of our Certificate of Incorporation, Bylaws, Rights Agreement plan and Delaware law may have an anti-takeover effect, these provisions are intended to enhance the likelihood of continuity and stability in the composition of the Board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control. In that regard, these provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our common stock that could result from actual or rumored takeover attempts. Such provisions also may have the effect of preventing changes in our management.

Exclusive forum for adjudication of disputes provision which limits the forum to the Delaware Court of Chancery for certain actions against the Company.

Our Bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the Delaware General Corporation Law or our Certificate of Incorporation or Bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine, except, in each case for claims arising under the Securities Act of 1933, as amended, the Exchange Act, or other federal securities laws for which there is exclusive federal or concurrent federal and state jurisdiction.

We believe limiting state law based claims to Delaware will provide the most appropriate outcomes as the risk of another forum misapplying Delaware law is avoided, Delaware courts have a well-developed body of case law and limiting the forum will preclude costly and duplicative litigation and avoids the risk of inconsistent outcomes. Additionally, Delaware Chancery Courts can typically resolve disputes on an accelerated schedule when compared to other forums. While we believe limiting the forum for state law based claims is a benefit, shareholders could be inconvenienced by not being able to bring certain actions in another forum they find favorable.

Delaware Takeover Statute

In general, Section 203 of the Delaware General Corporation Law prohibits a Delaware corporation that is a public company from engaging in any "business combination" (as defined below) with any "interested stockholder" (defined generally as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with such entity or person) for a period of three years following the date that such stockholder became an interested stockholder, unless: (1) prior to such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (2) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (x) by persons who are directors and also officers and (y) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (3) on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 of the Delaware General Corporation Law defines “business combination” to include: (1) any merger or consolidation involving the corporation and the interested stockholder; (2) any sale, transfer, pledge or other disposition of ten percent or more of the assets of the corporation involving the interested stockholder; (3) subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; (4) any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or (5) the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

Listing of Common Stock on the Nasdaq Capital Market

Our common stock is currently listed on the Nasdaq Capital Market under the trading symbol “HTBX.”

Transfer Agent

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. They are located at 1 State Street, 30th floor, New York, New York 10004. Their telephone number is (212) 509-4000.

EXHIBIT 21.1

Sssubsidiaries

Name of Subsidiary	Jurisdiction
Heat Biologics I, Inc	Delaware
Heat Biologics III, Inc.	Delaware
Heat Biologics IV, Inc.	Delaware
Heat Biologics GmbH.	Germany
Heat Biologics Australia Pty LTD	Australia
Zolovax, Inc.	Delaware
Pelican Therapeutics, Inc.	Delaware
Delphi Therapeutics, Inc.	Delaware
Scorpion Biosciences, Inc.	Delaware

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Heat Biologics, Inc.
Morrisville, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-224039 and No. 333-234105), Form S3 (No. 333-214868 and No. 333-221201) and Form S-8 (No. 333-193453, No. 333-196763, No. 333-207108, No. 333-213133, No. 333-219238, No. 333-227699, No. 333-233352 and No. 333-237137) of Heat Biologics, Inc. of our report dated March 30, 2020, relating to the consolidated financial statements, which appear in this Form 10-K. Our report on the consolidated financial statements contains an explanatory paragraph regarding Heat Biologics, Inc.'s ability to continue as a going concern.

/s/ BDO USA, LLP

BDO USA, LLP
Raleigh, NC

March 30, 2020

EXHIBIT 31.1

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

I, Jeffrey Wolf, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2020

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

(Principal Executive Officer)

EXHIBIT 31.2

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

I, William Ostrander, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 30, 2020

By: /s/ William Ostrander
Name: William Ostrander
Title: Vice President of Finance

(Principal Financial and Principal Accounting Officer)

EXHIBIT 32.1

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

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

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 30, 2020

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

EXHIBIT 32.2

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

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

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 30, 2020

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