

HEAT BIOLOGICS, INC.  
Form 10-K  
March 02, 2018

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, DC 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2017**

**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**

*(State or Other Jurisdiction of Incorporation or Organization)*

**26-2844103**

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

**801 Capitola Drive  
Durham, NC**

*(Address of Principal Executive Offices)*

**27713**

*(Zip Code)*

**(919) 240-7133**

*(Registrant's telephone number, including area code)*

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

<b>Title of Class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.0002 par value per share	The NASDAQ Capital Market

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

None

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
(Do not check if a smaller reporting company)		Emerging growth company	<input type="checkbox"/>

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based on the closing price of the common stock on June 30, 2017 as reported on The NASDAQ Capital Market, was approximately \$20,543,626.

As of February 28, 2018, the issuer had 4,756,069 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 . 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 developing approaches to activate and co-stimulate a patient's immune system against cancer. Our co-stimulatory antibody is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram the immunity and provide a long-term, durable clinical effect. Our T-cell activating platform (TCAP) produces therapies designed to turn immunologically cold tumors hot, and be administered in combination with checkpoint inhibitors and other immuno-modulators to increase clinical

effectiveness. Unlike many other patient specific immunotherapy approaches, our drugs are off-the-shelf which means that we can administer drug immediately without extracting patient material at a substantially lower cost of goods sold. Our TCAP product candidates from our *ImPACT*<sup>®</sup> and *ComPACT* platforms are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer (NSCLC), in combination with Bristol-Myers Squibb's nivolumab (Opdivo<sup>®</sup>). We also have numerous preclinical programs at various stages of development.

Through our *ImPACT*<sup>®</sup> platform technology our initial TCAP, we have developed product candidates that consist of live, allogeneic *off-the-shelf* genetically-modified, irradiated human cancer cells. These cells secrete a broad spectrum of Cancer Testis Antigens (CTAs), classified functionally as tumor-specific neoantigens, together with the gp96 protein. Our *ImPACT*<sup>®</sup> technology achieves this by reprogramming live tumor cells to secrete gp96 to serve as a chaperone for tumor antigens to activate and expand T-cell immunity; thereby, transforming the allogeneic cells into machines that have been shown to activate a robust killer CD8+ T cell immune attack against a patient's cancer. Unlike autologous or personalized monotherapy approaches that either require the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment, our product candidates are fully allogeneic, and do not require extraction of individual patient's material or custom manufacturing. As a result, our product candidates can be mass-produced and have the ability to be readily available for immediate patient use. Because each patient receives the same treatment, we believe that our immunotherapy approach offers logistical, manufacturing and other cost benefits, compared to patient-specific or precision medicine approaches.



Our Combination Pan-antigen Cytotoxic Therapy (*ComPACT*) our second TCAP, is a dual-acting immunotherapy designed to deliver T-cell activation and enhanced, T-cell specific co-stimulation in a single treatment. *ComPACT* helps unlock the body's natural defenses and builds upon *ImPACT* by also providing alternative co-stimulation targeting enhanced T-cell activation and expansion. It has the potential to simplify combination immunotherapy development with enhanced safety for oncology patients, as it is designed to deliver the gp96 heat shock protein with each selected tumor cell line's neoantigens (CTAs) and a T-cell co-stimulatory fusion protein (e.g. OX40L) into a single intradermal treatment. *ComPACT* serves as a booster to expand the number of antigen-specific T-cells compared to co-stimulator alone, while also enhancing the activation of cancer antigen-specific CD8+ memory T-cells for an extended time after treatment. *ComPACT* has the potential to be a cost-effective approach compared to conventional immunotherapies.

Pelican Therapeutics, Inc. ( Pelican ), a subsidiary of Heat, is a biotechnology company focused on the development of monoclonal antibody and fusion protein-based therapies designed to activate the immune system. PTX-35, which is currently in preclinical IND enabling activities, is Pelican's lead product candidate targeting the T-cell co-stimulator, TNF receptor superfamily member 25 (TNFRSF25). It is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram the immunity and provide a long-term, durable clinical effect. When combined with immunotherapies, including the *ImPACT*® and *ComPACT* platform technologies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. PTX-15, Pelican's second product candidate, is a human TL1A-Ig fusion protein designed as a shorter half-life agonist of TNFRSF25.

In June 2016, Pelican was awarded a \$15.2 million Cancer Prevention Institute of Texas (CPRIT) grant (the CPRIT Grant ) to support further development of PTX-35 and fund a Phase 1 clinical trial to examine potential benefits to patients with several types of cancers, such as lung, lymphoma, prostate, pancreatic and ovarian.

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

## **Product Candidates in Development**

The following table summarizes the product candidates for which we are engaged in development activities. Heat and Pelican's combined pipeline is focused on dual-acting immunotherapies that incorporate a T-cell antigen driven activator and a T-cell co-stimulator into a single treatment.



## **Clinical Pipeline**

### *HS-110 (viagenpumatucl-L) Non-Small Cell Lung Cancer (NSCLC)*

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

We are currently conducting a Phase 2 trial of HS-110, in combination with nivolumab (Opdivo<sup>®</sup>), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, to treat patients with NSCLC. The multicenter clinical trial evaluates the safety and efficacy of HS-110 in combination with nivolumab in patients with advanced NSCLC whose cancers have progressed after one or more lines of therapy. Promising interim results for the first 15 patients enrolled suggest HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients. Primary and secondary trial endpoints include safety and tolerability, immune response, objective response rate, duration of response, and progression-free and overall survival. The trial enrolled 15 patients into the Phase 1b portion, and initiated enrollment in the Phase 2 portion of the trial in March 2017.

## **Preclinical Pipeline**

### *HS-130*

We have initiated the IND-enabling development of HS-130 for the treatment of NSCLC. This product will utilize our *ComPACT* technology, which is designed to intradermally deliver both cellularly secreted cancer associated antigens bound to a secretory version of the gp96 heat shock protein, as well as a T-cell co-stimulatory fusion protein (e.g. OX40L). We have begun manufacturing activities for this product candidate.

### *PTX-35*

Pelican is focused on the development of monoclonal antibody and fusion-protein based therapies designed to activate the immune system. Pelican is currently in preclinical studies for its lead compound 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 antigen specific memory CD8+ cytotoxic T-cells. These cells are instrumental in eliminating cancer cells. Prior to our acquisition of 80% of Pelican, Pelican had completed (1) humanization and affinity maturation of PTX-35; (2) PTX-35 epitope mapping or mapping of the binding site on the TNFRSF25 receptor that is recognized by PTX-35; and (3) stability/development studies of PTX-35. We have begun manufacturing activities for this product candidate.

The preclinical studies with the murine precursor to PTX-35 show advantages over competing T-cell co-stimulator programs based on the specific expansion of CD8+ cancer specific T-cells.

### ***PTX-15***

PTX-15 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. We have begun manufacturing activities for PTX-15.

### **Additional Indications**

We continue to evaluate additional indications for the *ImPACT*<sup>®</sup> and *ComPACT* platform technologies, along with the PTX-35 and PTX-15 compounds. Specifically, using *ComPACT*, we have developed cell lines for several other cancers with the first product candidate being a second-generation therapy for NSCLC (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*<sup>®</sup> 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.



## Recent Developments

On February 27, 2018, we presented interim results at the 2018 Keystone Symposia Conference, Immunological Memory: Innate, Adaptive and Beyond (XI1) from our Phase 2 study, investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced NSCLC whose cancers have progressed after treatment with one or more lines of therapy.

Among the 35 patients in the Intent-to-Treat (ITT) population, 6 patients (17%) achieved a partial response and 14 patients (40%) achieved disease control. Evaluable ITT patients (those who underwent at least one follow-up scan regardless of treatment duration) demonstrated overall response and disease control rates of 26% and 67%, respectively. Overall responses appeared durable and long lasting. The survival data are still maturing, and median overall survival has not yet been reached. The combination of HS-110 and nivolumab was well tolerated, with no additional toxicities compared to what has been observed with single agent checkpoint inhibitors.

As predefined in the clinical protocol, patient subgroups were evaluated for levels of tumor infiltrating lymphocytes (TIL) and for PD-L1 checkpoint protein expression on tumor cells. Four of 9 cold tumor patients with low TIL levels (<10%) at baseline had partial responses. HS-110 also showed a durable effect in patients with low levels of PD-L1, with 3 of 9 patients responding. Both of these patient populations respond poorly to checkpoint inhibitors.

## 2017 Developments

On December 7, 2017, we received written responses from the U.S. Food and Drug Administration (the "FDA") following a granted Type C meeting regarding the planned registrational HS-110 clinical trial design for the treatment of NSCLC. The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

On October 30, 2017, Pelican received the second tranche in the amount of \$6.5 million of its \$15.2 million CPRIT Grant award. The CPRIT award supports the pre-clinical development, manufacturing and clinical development of a 70-patient, Phase 1 clinical trial for PTX-35.

On September 27, 2017, we announced a manufacturing agreement with KBI Biopharma, Inc. a global biopharmaceutical contract development and manufacturing organization, for cGMP product of Pelican's PTX-35 antibody and PTX-15 fusion protein. Under the agreement, KBI Biopharma will offer comprehensive development and manufacturing services, which is expected to offer advantages such as speed, productivity, stability and flexibility over traditional approaches to cell line development.

On June 28, 2017, Pelican reported that it was on track to meet product development milestones and received the first tranche in the amount of approximately \$1.8 million of its \$15.2 million CPRIT Grant award.

On May 1, 2017, we announced the completion of the acquisition of an 80 percent controlling interest in Pelican.

On March 21, 2017, we reported promising interim results for the Phase 1b portion of the trial evaluating HS-110 in combination with Bristol-Myers Squibb's checkpoint inhibitor, nivolumab (Opdiv<sup>®</sup>), for the treatment of advanced NSCLC.

### ***ImPACT<sup>®</sup>/ComPACT Platform Technology Advantages***

We seek to increase the percentage of patients responding to checkpoint inhibitors with a combination treatment that is designed to activate the immune defense mechanisms to seek out and kill cancer cells. *ImPACT<sup>®</sup>* and *ComPACT*, the TCAP therapies, have been shown to stimulate an immune response against the full antigenic repertoire of cancer cells, not just one or a handful of antigens. The technologies are designed to combine a broad antigen targeting of known CTAs and unknown tumor associated antigens, complexed with a potent immune adjuvant. The activated immune response generated by our TCAP therapies may be useful in treating a wide range of cancers and infectious diseases.





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*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 patient to elicit an immune response against the patient's own tumor. The treatment primes immune recognition and triggers the body to stimulate the adaptive, T-cell mediated immune system to seek and destroy the cancer cells.

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

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*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 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.

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*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, 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.

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*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-15 Advantages**

Pelican provides access to two T-cell co-stimulators 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 and 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 and eliminate tumor cells in patients. This approach is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity, and provide a long-term, durable therapeutic effect. When combined with immunotherapies, including the *ImPACT*<sup>®</sup> 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-15 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.

## 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 two synergistic mechanisms of action: robust activation of cancer-specific killer T-cells and T-cell co-stimulation 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 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 other therapies, such as checkpoint inhibitors, which are designed to reverse tumor-induced immune suppression. We are focused on discovering, developing, and applying the *ImPACT*<sup>®</sup> and *ComPACT* platform technologies; and our PTX-35/PTX-15 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 are currently enrolling patients in the Phase 2 portion of the HS-110 trial in combination with nivolumab (Opdivo<sup>®</sup>), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor to treat patients with advanced NSCLC. Beyond NSCLC – depending upon funding and partnering opportunities – we plan to expand the current clinical trial in additional patient populations and initiate new clinical trials with added immune modulators.

*Maximize commercial opportunity for the ImPACT<sup>®</sup> and ComPACT technology, as well as our PTX-35 and PTX-15 compounds.* Our current product candidates target large markets with significant unmet medical needs. For each of our product candidates, we seek to retain all manufacturing, marketing and distribution rights, which should give us the ability to maximize the economic potential of any future U.S. or international commercialization efforts.

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

*Further expand our broad patent portfolio.* We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to do so. We have obtained exclusive rights to six different patent families directed to therapeutic compositions and methods related to our platform and preclinical development programs for cancer, and have filed certain additional patent applications that are owned by us. The *ImPACT*<sup>®</sup>/*ComPACT* patent portfolio comprise more than 13 issued patents and 20 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 34 granted U.S. and foreign patents, and approximately 16 U.S. and foreign patents 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 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.

## **The Oncology Market and Current Treatments**

The American Cancer Society estimates that 1.7 million people in the United States will be diagnosed with cancer in 2018. The lifetime probability of being diagnosed with an invasive cancer is 39.7% for men and 37.6% for women. It is projected that 609,000 Americans will die from cancer in 2018.



Lung cancer is the second-most commonly diagnosed cancer in the U.S. An estimated 222,500 new cases of lung cancer were diagnosed in 2017, accounting for about 25% 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 15% for men and 21% for women. Only 16% of lung cancers are diagnosed at a localized stage, for which the five-year survival is 55%. The American Cancer Society estimates that one in four deaths in the United States is due to cancer.

## **Pelican Acquisition**

On March 7, 2017, we entered into a Stock Purchase Agreement (the **Purchase Agreement**) with Pelican, a related party and certain stockholders of Pelican holding a majority of the outstanding shares (the **Majority Pelican Stockholders**) to purchase shares of the outstanding capital stock of Pelican (the **Pelican Acquisition**). The Purchase Agreement was conditioned upon the holders of at least 80% of the outstanding capital stock of Pelican on a fully diluted basis participating in the Pelican Acquisition. On April 28, 2017, we closed the Pelican Acquisition (the **Closing**) and additional Pelican stockholders executed Joinders to the Purchase Agreement (the **Additional Participating Pelican Stockholders**, together with the Initial Participating Pelican Stockholders, collectively, the **Participating Pelican Stockholders**). The Participating Pelican Stockholders included Jeff 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. Each Participating Pelican Stockholder exchanged approximately 84.7% of the shares of Pelican common stock held by such Participating Pelican Stockholder in exchange for a pro rata share of (i) an aggregate of 133,106 shares, adjusted for the one-for-ten reverse stock split effective January 19, 2018 (the **Stock Consideration**) of our restricted common stock, and (ii) aggregate cash consideration of \$0.5 million (the **Cash Consideration**), all of which was held in escrow for a period of up to six (6) months to secure certain indemnification and other obligations of Pelican and the Participating Pelican Stockholders in connection with the Pelican Acquisition and of which is currently being distributed to the Participating Pelican Stockholders.

In addition to the payments described above, under the terms of the Purchase Agreement, we agreed to cause Pelican to make cash payments to the Participating Pelican Stockholders upon the achievement of certain clinical and commercialization milestones set forth below, as well as low single digit royalty payments and payments upon receipt of sublicensing income, all as described in more detail in the Purchase Agreement:

- (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 a \$15.2 million grant to fund preclinical and some clinical activities from CPRIT. The CPRIT Grant is subject to customary CPRIT funding conditions. We have provided Pelican approximately \$1.2 million to satisfy Pelican's matching fund obligation under the first two years of the CPRIT Grant and Pelican has received approximately \$8.3 million CPRIT Grant funding to date.

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.



## **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-25. The CPRIT Grant is expected to allow Pelican to develop PTX-25 through a 70-patient Phase 1 clinical trial. The Phase 1 clinical trial will be designed to evaluate PTX-25 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 three year project.

As of December 31, 2017, we have provided approximately \$1.2 million in matching funding and we have \$6.4 million remaining to provide over the three-year project, with \$2.9 million remaining for the second CPRIT fiscal year (June 2017 through May 2018) of the award, and \$3.5 million for the third CPRIT fiscal year (June 2018 through May 2019).

As of December 31, 2017, CPRIT has provided \$8.3 million of the total \$15.2 million grant. The remaining \$6.9 million will become available in the third CPRIT fiscal year (June 2018 through May 2019).

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.

## **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*<sup>®</sup> 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 the University of Miami. *ImPACT*<sup>®</sup>, PTX-15, and PTX-35 are protected by issued patents and various pending patent applications while *ComPACT* is protected by pending patent applications. In total, Heat holds approximately 13 granted U.S. and foreign patents and approximately 20 U.S. and foreign patents pending. In total, Pelican holds approximately 34 granted U.S. and foreign patents and approximately 16 U.S. and foreign patents pending.

Heat's foundational *ImPACT*<sup>®</sup> patent coverage is from the Modified Heat Shock Proteins-Antigenic Peptide Complex patent family, which is exclusively licensed from the University of Miami (the University), and granted as US Patent No. 8,685,384. This patent expires in 2019, not including any patent term adjustments or extensions. Further *ImPACT*<sup>®</sup> 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 pending in 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 University of Miami and provide protection to 2029 (not including any patent term adjustments or extensions). Various recently filed provisional patent applications assigned to Heat and relating to *ImPACT*<sup>®</sup> are also pending.

Heat's *ComPACT* technology is covered by 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 patent applications assigned to Heat and related to *ComPACT* are also pending.

Pelican's PTX-15 and PTX-35 coverage stems from three exclusive license agreements with the University of Miami (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-15 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-15 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. Recent patent applications assigned to Pelican are intended to provide further compositional coverage for PTX-35.

## 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 the University shares of its common stock representing seven and one-half percent (7.5%) of its common stock. The term of the license is the length of the last to expire patent, unless terminated earlier. The license agreement grants Heat Biologics I, Inc. exclusive, worldwide rights to make, use or sell licensed materials based upon the 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 1, Inc. pursuant to the terms of an exclusive license agreement that was entered into with the University in February 2011 and 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 the University 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 the University 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 the University 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 the University. In the event of a termination, Heat Biologics I, Inc. will be obligated to pay all amounts that accrued prior to such termination. Each of the above license agreements also contains other customary clauses and terms as are common in similar agreements between industry and academia, including the licensee's agreement to indemnify the University for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

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 the University for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases. 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 the University equal to a percentage of sublicense income. The license agreement provides for diligence milestone 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 the University 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 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 the University, Pelican has obtained exclusive rights to five 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 34 granted U.S. and foreign patents, and approximately 16 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 the University, Pelican issued the University 300,000 shares of its common stock.

As consideration for the rights granted under the initial license agreement, Pelican is obligated to pay the University certain upfront license fees, aggregate milestone payments of \$400,000 ((i) upon submission of an IND, (ii) approval of an IND, (iii) completion of a Phase 1 clinical trial and (iv) 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, Pelican is obligated to pay the University certain upfront license fees, aggregate milestone payments of \$650,000 ((i) upon submission of an NDA, (ii) approval of a NDA; (iii) completion of Phase 1 clinical trial and (iv) 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, Pelican is obligated to pay the University 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 the University provides that in the event that Pelican terminates its second license agreement with the University, Pelican is obligated to pay the University an annual minimum royalty payment of \$20,000 for each year after 2014 during the term of the third license agreement as well as milestone payments that aggregate \$400,000 upon achievement of the following milestones: (i) submission of an IND; (ii) approval of a NDA; (iii) completion of a Phase 1 clinical trial; and (iv) 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 the University 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 the University 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 the University. 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 the University for liabilities arising out of the negligence of the licensee, making the license grant subject to the Bayh-Dole act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

## **Manufacturing**

We rely on third-party manufacturers to produce and store our product candidates for clinical use and currently do not own or operate manufacturing facilities.

We have retained Lonza, Inc. a vendor, which has begun manufacturing of HS-110 to be used in our Phase 2 and potential Phase 3 clinical trials. We entered into an eight-year Manufacturing Services Agreement, dated October 20, 2011, with the vendor (the Manufacturing Agreement ). The Manufacturing Agreement provides that the vendor will manufacture products based on our *ImPACT*<sup>®</sup> technology intended for use in pharmaceutical or medicinal end products, including, without limitation, products in a final packaged form and labeled for use in clinical trials or for commercial sale to end users in accordance with the terms and conditions of individual statements of work. The Manufacturing Agreement requires that we purchase a certain minimum percentage of our annual global product requirements from the vendor. The Manufacturing Agreement may be terminated by the parties upon mutual agreement, and by each party for a material breach by the other party that is not cured within the cure period, upon notice that a clinical trial for which product is being produced under the agreement is suspended or terminated or upon the other party's insolvency, dissolution or liquidation.

The HS-110 product used in the inventor's Phase 1, and in our Phase 2 clinical trial continues to be manufactured under cGMP (current good manufacturing practices). The vaccine cell line is grown in large quantities, dispensed into individual doses, frozen in liquid nitrogen, irradiated to render cell replication incompetent and quality tested in compliance with FDA guidelines. The vaccine is irradiated, which is a commonly used attenuation process that eliminates the ability of the gp96-Ig-containing vaccine cell lines to replicate but allows them to remain metabolically active and secrete gp96-Ig. The batches of frozen, irradiated vaccine are stable for long periods of time, and are thawed immediately prior to administration to patients. Sufficient material to dose a subset of patients in the HS-110 clinical studies has already been produced, and preparations are underway to produce quantities required for trial completion and subsequent clinical trials.



Heat has also begun development of an additional product, HS-130, for treatment of NSCLC. This product will utilize our *ComPACT* technology, which is designed to deliver the gp96 heat shock protein and a T-cell co-stimulatory fusion protein (OX40L). We have begun the cGMP manufacturing and nonclinical IND enabling activities to support the clinical development of this product.

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 retained KBI Biopharma, a vendor, for development of two products; PTX-35 and PTX-15. PTX-35 is 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 class of T-cell that is responsible for eliminating tumor cells in patients. PTX-15 is a human TL1A-Ig fusion protein with many of the same functional qualities of PTX-35 but a shorter in vivo half-life. Pelican has begun the nonclinical IND enabling activities to support the clinical development of these products.

## **Competition**

The pharmaceutical industry and biologics industry are each highly competitive and characterized by a number of established large companies, and mid-sized companies, as well as smaller companies like ours. If our competitors market products that are less expensive, safer or more effective than any future products developed from our product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to our research and development activities. As a biotechnology company with cancer immunotherapy agents as lead product candidates, we compete with a broad range of companies. At the highest level, cancer immunotherapy can be seen as both a complement and a potential competitor to any oncology therapy, most notably chemotherapy, radiotherapy, biologics and small molecule drugs. Not only do we compete with companies engaged in various cancer treatments including radiotherapy and chemotherapy but we also compete with various companies that have developed or are trying to develop immunology vaccines for the treatment of cancer. Certain of our competitors have substantially greater capital resources, large customer bases, broader product lines, sales forces, greater marketing and management resources, larger research and development staffs with extensive facilities and equipment than we do and have more established reputations as well as global distribution channels. Our most significant competitors, among others, are fully integrated pharmaceutical companies such as Eli Lilly and Company, Bristol-Myers Squibb Company, Merck & Co., Inc., Novartis AG, MedImmune, LLC (a wholly owned subsidiary of AstraZeneca plc), Johnson & Johnson, Pfizer Inc., MerckKGaA and Sanofi SA, and more established biotechnology companies such as Genentech, Inc. (a member of the Roche Group), Amgen Inc., Celgene Corporation, Gilead Sciences, Inc. and its subsidiary Kite Pharma, Inc., and competing cancer immunotherapy companies such as, Juno Therapeutics, Inc., Bluebird Bio, Inc., Transgene SA, Valeant Pharmaceuticals International, Inc., NewLink Genetics Corporation, Agenus Inc., NovaRx Corporation, Aduro Biotech, Inc., Advaxis, Inc., ImmunoCellular Therapeutics, Ltd., Immunovaccine Inc., Oxford BioMedica plc, Bavarian Nordic A/S, Celldex Therapeutics, Inc., Telesta Therapeutics Inc. and others, some of which have substantially greater financial, technical, sales, marketing, and human resources

than we do. These companies might succeed in obtaining regulatory approval for competitive products more rapidly than we can for our products. In addition, competitors might develop technologies and products that are less expensive, safer or more effective than those being developed by us or that would render our technology obsolete. In addition, the pharmaceutical and biotechnology industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to remain current with the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our technologies obsolete by advancing their existing technological approaches or developing new or different approaches.

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

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

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

.

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, 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<sup>®</sup> (nivolumab), Keytruda<sup>®</sup> (pembrolizumab), Alimta<sup>®</sup> (pemetrexed), Avastin<sup>®</sup> (bevacizumab), Tarceva<sup>®</sup> (erlotinib), Gemzar<sup>®</sup> (gemcitabine), Paraplatin<sup>®</sup> (carboplatin), Taxol<sup>®</sup> (paclitaxel), Taxotere<sup>®</sup> (docetaxel), and Navelbine<sup>®</sup> (vinorelbine). It is unlikely that biologic agents will compete with more traditional therapies in the short-term, but many oncologists believe that such therapies will eventually become the mainstay of lung cancer therapy. None of these agents have proven particularly effective for stage IIIB/IV NSCLC patients, with the most effective therapies only increasing survival by a few months. As a result, we do not consider these agents to be direct competitors to HS-110 because they are likely to be given either in sequence or in conjunction with some of the agents listed. Furthermore, many patients cannot tolerate many of the chemotherapeutics listed. Thus, we believe if HS-110 has a positive safety profile (without observation of local or systemic toxicities, none of which have been seen to date), it is likely that HS-110 would be preferred both by physicians and patients in this stage of disease.

Our strategy is to emphasize what we believe to be our competitive advantages, which 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 \$2,421,459, 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 \$304,162. 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 12 months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for products intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

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

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

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

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

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



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

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

#### ***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*<sup>®</sup> technology meet this threshold and therefore are considered biological drugs. Manufacture of *ImPACT*<sup>®</sup> products are subject to both cGTP and cGMP regulations for manufacturing quality. Marketing of these products in the United States will require FDA approval under the BLA pathway as discussed above.

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

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

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

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

### **Research and Development**

We have built an internal and external research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical chemistry, manufacturing, clinical development and regulatory and quality assurance. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Our cancer trials have been registered on [clinicaltrials.gov](http://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 \$8.3 million and \$9.3 million during the years ended December 31, 2017 and 2016, respectively.

## **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 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. Our website address is [www.heatbio.com](http://www.heatbio.com). The information contained in, and that can be accessed through our website, is not incorporated into and is not a part of this report. We make available on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K as soon as reasonably practicable after those reports are filed with the U.S. Securities and Exchange Commission (the "SEC"). The following Corporate Governance documents are also posted on our website: Code of Conduct, Code of Ethics for Financial Management and the Charters for the 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) 305-8566. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street NE, Room 1580 Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://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. Heat formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012. Heat also formed Heat Biologics Australia Pty LTD, a wholly-owned company, registered in Australia on March 14, 2014. On October 25, 2016 Heat formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, dengue and yellow fever. On April 28, 2017, we completed the acquisition of an 80% controlling interest in Pelican, a related party prior to acquisition. In June 2012, we divested our 92.5% interest in Pelican (formerly known as Heat Biologics II, Inc.). We assigned our proprietary rights related to the development and application of our *ImPACT*<sup>®</sup> therapy platform to Heat Biologics I, Inc.

## **Employees**

As of December 31, 2017, we had a total of 19 full-time employees. We believe our relationships with our employees are satisfactory. None of our employees is represented by a labor union. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel to pursue our development program. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.



**Item 1A.**

***Risk Factors***

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

**Risks Relating to our Company**

*We have had limited operations to date.*

We are a clinical stage company and have had limited operations to date 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. Even if we generate revenue, 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:

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

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participating in regulatory approval processes;

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formulating and manufacturing products; and

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conducting sales and marketing activities.

While various members of our management and staff have significant experience in conducting cancer trials, the Company, to date, we have not successfully completed any late stage clinical trials and we have limited experience conducting and enrolling patients in clinical trials. Until recently, 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.

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

Our financial statements have been prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities, and the addition of Pelican's activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to its technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms 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 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, 2017 and 2016, we incurred a net loss of \$12.4 million and \$13.0 million, respectively. We have an accumulated deficit of \$68.8 million through December 31, 2017. Pelican has also incurred net losses, which are included in the net loss of \$12.4 million and \$13.0 million for the years ended December 31, 2017 and 2016, respectively, and when consolidated with our net losses, resulted in a larger net loss. 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:

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

·  
seek regulatory approvals for product candidates;

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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, 2017, our operating activities used net cash of approximately \$6.3 million and as of December 31, 2017, our cash and cash equivalents were approximately \$9.8 million. During the year ended December 31, 2016, our operating activities used net cash of approximately \$13.5 million and as of December 31, 2016 our cash and cash equivalents were approximately \$7.8 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2017, our accumulated deficit totaled approximately \$68.8 million and as of December 31, 2016, our accumulated deficit totaled approximately \$57.0 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 expect that our current cash and cash equivalents will allow us to continue the enrollment of additional patients in the Phase 2 clinical trial for HS-110; however, if the trial design or size were to change, we may need to raise money earlier than anticipated.

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

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

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

additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

*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. During the second quarter of 2017, we identified a material weakness in our controls over financial reporting related to the purchase price accounting for the acquisition that occurred during the quarter. Specifically, we did not design and maintain effective controls related to the acquisition for the purchase price of the acquired assets and liabilities of Pelican. Although the control deficiencies were remediated by the end of the fiscal year there can be no assurance that the internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

***We are substantially dependent on the success of our product candidates, only one of which is currently being tested in a clinical trial, 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 is in clinical stage development. 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 of 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 we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

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

### **Risks Relating to our Business**

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

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates or any product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a BLA, demonstrating that the product candidate is safe, pure and potent, or

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

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

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

In addition, the FDA may require us to conduct additional 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 is our only current product candidate in clinical trials and our other product candidates are all in the preclinical stage of development. Although we have commenced a Phase 2 clinical trial for HS-110, 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 26 patients 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.

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

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

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unforeseen safety issues;
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failure to determine appropriate dosing;
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greater than anticipated cost of our clinical trials;
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failure to demonstrate effectiveness during clinical trials;
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slower than expected rates of patient recruitment or difficulty obtaining investigators;
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patient drop-out or discontinuation;
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inability to monitor patients adequately during or after treatment;





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

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

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

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

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

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

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

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:

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

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

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cost-effectiveness of our products relative to competing products;

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convenience and ease of administration;

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potential advantages of alternative treatment methods;

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availability of reimbursement for our products from government or other healthcare payers; and  
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effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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

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

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

We have developed certain experience in the formulation, development and/or manufacturing of biologics but do not intend to establish our own manufacturing facilities. To date, the selection and initial replication of our biological cell lines used in our trials has been performed by individuals working at third party laboratories over which we have little process or quality control and therefore the process and replication could be subject to human error. We lack the resources and expertise to formulate or manufacture our own product candidates. The investigational products for our clinical trials are manufactured by our contractors under current good manufacturing practices, ( cGMPs ) and we have entered into agreements with commercial-scale manufacturers for the production and supply of investigational product for additional Phase 2 and Phase 3 clinical trials as well as commercialization. Our agreement with the manufacturer of our HS-110 product expires in October 2019, and we have no assurance that we can extend current agreement or renegotiate our agreement on favorable terms if at all. 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.

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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.

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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.

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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.

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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.

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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.

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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 another immunotherapy agent. Any problems obtaining the other immunotherapy agent 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. Therefore, our success will be dependent upon the continued use of this 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 or 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:

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

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

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

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

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

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

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

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

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

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

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have oncology compounds already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and

development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

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

***We have limited protection for our intellectual property, 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 expire 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:

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

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abandon an infringing drug or therapy candidate;

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redesign our products or processes to avoid infringement;

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

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pay damages; or

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

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

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



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

For the years ended December 31, 2018, 2019, 2020, 2021, and 2022 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 \$64,000, \$74,000, \$103,000, \$228,000 and \$784,000, respectively. No assurance can be given that we will generate sufficient revenue or raise additional financing to make these minimum royalty payments. The license agreements also provide for certain developmental milestones, 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. Any failure to make the payments or reach the milestones required by the license agreements would permit the licensor to terminate the license. If we were to lose or otherwise be unable to maintain these licenses, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

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

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

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government and health administration authorities;

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private health maintenance organizations and health insurers; and

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other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and therapeutics. We might need to conduct

post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payers satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such 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, uncertainty remains regarding proposed significant reforms to the U.S. health care system.

***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. 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. In particular, over the next 12 months, we expect to hire additional new employees both in North Carolina and for Pelican 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. Attracting and retaining qualified personnel will be critical to our success.

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

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

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



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

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

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

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

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difficulties in managing foreign operations;

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

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

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

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reduced protection for intellectual property rights;

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

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 recent acquisition of 80% of the equity of Pelican, we have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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

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

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

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

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

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

#### **Risk Factors Relating to the Pelican Acquisition (the Acquisition )**

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

Neither we nor Pelican are expected to derive revenue from any source in the near future until they or 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 three years, Pelican must raise matching funds in the aggregate amount of approximately \$7.6 million. Pelican has received from us matching funds in the amount of approximately \$1.2 million as of December 31, 2017. CPRIT has made available to Pelican the grant award in the amounts of approximately \$1.8 million for the first contract fiscal year (June 2016 - May 2017) and approximately \$6.5 million for the second contract fiscal year (June 2017 - May 2018). Pelican must provide matching funds of approximately \$3.2 million for the second fiscal year grant. For the third fiscal year (June 2018 through May 2019) of the award Pelican must provide matching funds of approximately \$3.5 million in order for CPRIT to provide approximately \$7.0 million of grant funding. In addition, we have agreed to provide Pelican approximately \$0.3 million to pay Pelican's legal fees and expenses incurred in connection with the Acquisition. Our financial statements have been prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities, and the addition of Pelican's activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to 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.

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

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

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

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

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

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

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- assimilating Pelican's technology and retaining personnel in Texas as required by the CPRIT Grant award;

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estimating the capital, personnel and equipment required for Pelican based on the historical experience of management with the businesses they are familiar with;

.

minimizing potential adverse effects on existing business relationships;

.

successfully developing the new products and services; and

.

coordinating our efforts throughout various distant localities such as Texas where Pelican is headquartered and must remain headquartered in order to access the CPRIT Grant award.

### **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. On March 15, 2017, we received written notice from the Listing Qualifications Department of NASDAQ Stock Market LLC (NASDAQ) notifying us that for the preceding 30 consecutive business days (January 31, 2017 through March 14, 2017), our common stock did not maintain a minimum closing bid price of \$1.00 per share (Minimum Bid Price Requirement) as required by NASDAQ Listing Rule 5550(a)(2). On September 12, 2017, we received written notice from NASDAQ that we had been granted an additional 180-day extension, or until March 12, 2018, to regain compliance with the Minimum Bid Price Requirement. On January 19, 2018, we effected a one-for-ten reverse split of our common stock in order to regain compliance with The NASDAQ Minimum Bid Price Requirement. On February 5, 2018, we were notified by The NASDAQ that we had regained compliance with the Minimum Bid Price Requirement and that the matter was closed. No assurance can be given that we will continue to remain compliant with The NASDAQ Minimum Bid Price Requirement or NASDAQ's other continued listing requirements.



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

***The sale or issuance of our common stock through the Common Stock Sales Agreement that we entered into in January 2018 with H.C. Wainwright & Co., LLC may cause dilution.***

On January 18, 2018, we entered into a common stock sales agreement (the "H.C. Wainwright Sales Agreement") with H.C. Wainwright & Co., LLC pursuant to which we may offer and sell shares of our common stock through H.C. Wainwright & Co., LLC as our sales agent. The purchase price for the shares that we may sell under the H.C. Wainwright Sales Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of shares under the H.C. Wainwright Sales Agreement may cause the trading price of our common stock to fall. Additionally, further sales of our common stock, if any, under the H.C. Wainwright Sales Agreement will depend upon market conditions and other factors to be determined by us. Therefore, sales under the H.C. Wainwright Sales Agreement by us could result in substantial dilution to the interests of other holders of our common stock.

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

In 2009, we adopted a 2009 Incentive Stock Plan (the "2009 Plan"). In 2014, we adopted a 2014 Stock Incentive Plan (the "2014 Plan") and, in 2016 and 2015, we increased the number of shares of common stock that we have authority to grant under the 2014 Plan to a total of 3 million shares (300,000 shares post-reverse stock split). In addition, at our 2017 Annual Meeting of Stockholders, our 2017 Stock Incentive Plan (the "2017 Plan") was approved by our stockholders, which provides for the issuance of up to 5,000,000 shares of common stock (500,000 shares of common stock post-reverse stock split) as compensation awards. As of December 31, 2017, post-reverse stock split awards for (i) 23,998 shares of common stock are outstanding under the 2009 Plan, (ii) 254,591 shares of common stock are outstanding under the 2014 Plan, and (iii) 10,000 shares of common stock are outstanding under 2017 Plan which resulted in on a post-reverse stock split basis (i) 34,047 shares of common stock, (ii) 29,149 shares, and (iii) 490,000 shares of common stock, respectively, remaining available for grants under the 2009 Plan, 2014 Plan, and 2017 Plan, respectively.

In addition, as of December 31, 2017, we have issued warrants exercisable for 1,738 shares of our common stock on a post-reverse stock split basis to third parties in connection with prior private placements of our equity securities and debt, warrants exercisable for 296,159 shares of our common stock on a post-reverse stock split basis to third parties

in connection with a public offering, and warrants exercisable for 12,500 shares of our common stock on a post-reverse stock split basis to underwriters in connection with our initial public offering. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

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

Our certificate of incorporation authorizes the issuance of 100,000,000 shares of our common stock and 10,000,000 shares of preferred stock. In certain circumstances, the common stock and preferred stock, as well as the awards available for issuance under the 2009, 2014, and 2017 Plans, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of preferred stock and common stock. In addition, the issuance of preferred stock may be used as an anti-takeover device without further action on the part of our stockholders, and may adversely affect the holders of the common stock. Our board of directors is authorized to create and issue from time to time, without stockholder approval, up to an aggregate of 10,000,000 shares of preferred stock of which 8,212,500 have been designated, in one or more series and to establish the number of shares of any series of preferred stock and to fix the designations, powers, preferences and rights of the shares of each series and any qualifications, limitations or restrictions of the shares of each series. 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.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act enacted in April 2012, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board, or the PCAOB, requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 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 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to stockholders of such companies.

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

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

On February 28, 2018, we had 4,756,069 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our stockholders might sell significant shares of our common stock could also depress the market price of our common stock.

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



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

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

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

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

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

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

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

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

*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 (post-reverse stock split) and issued warrants to underwriters in connection with our initial public offering that have an exercise price of \$125.00 per share (post-reverse stock split). 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 the H.C. Wainwright Sales Agreement may be sold in at the market offerings, and investors who buy shares at different times will likely pay different prices.***

On January 18, 2018, we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC (the H.C. Wainwright Sales Agreement ). Investors who purchase shares that are sold under the H.C. Wainwright Sales Agreement at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

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

Securities research analysts, including those affiliated with our underwriters 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 management team may invest or spend the proceeds of our prior offerings in ways with which stockholders may not agree or in ways that may not yield a significant return.***

Our management will have broad discretion over the use of proceeds from our November 2017 public offering, our at-the-market offering with H.C. Wainwright, and additional future financings. The net proceeds from these offerings are to be used for general corporate purposes, which may include, among other things, increasing our working capital, funding research and development, clinical trials, vendor payables, potential regulatory submissions, hiring additional personnel and capital expenditures. Our management has considerable discretion in the application of the net proceeds, and stockholders will not have the opportunity to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our operating results or enhance the value of our common stock.

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

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

**Item 1B.**

*Unresolved Staff Comments*

None.

**Item 2.**

*Properties*

**Facilities**

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

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 \$9,238, exclusive of payments required for maintenance of common areas and utilities. We anticipate Pelican's occupancy by March 31, 2018.

**Item 3.**

*Legal Proceedings*

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

**Item 4.**

*Mine Safety Disclosures*

Not applicable.

## PART II

### Item 5.

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

Our common stock has traded on the NASDAQ Capital Market under the symbol `HTBX` since July 29, 2013. Prior to that time, there was no public market for our common stock. The following table states the range of the high and low sales prices of our common stock for the year ended December 31, 2016, and the year ended December 31, 2017 and the first fiscal quarter of 2018, through February 28, 2018 (as adjusted to reflect the one-for-ten reverse stock split effective January 19, 2018). These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NASDAQ on February 28, 2018 was \$2.52 per share. As of February 28, 2018, there were approximately 65 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name.

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. ET 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 annual stockholders meeting held June 29, 2017, shareholders approved our company's reverse stock split, and granted the board of directors the authority to implement and determine the exact split ratio. When the reverse stock split became effective, every 10 shares of our issued and outstanding common stock were combined into one share of common stock. Effecting the reverse stock split reduced the number of issued and outstanding common stock from approximately 42 million shares to approximately 4.2 million. It also subsequently adjusted outstanding options issued under our equity incentive plan and outstanding warrants to purchase common stock.

	<b>High</b>	<b>Low</b>
YEAR ENDED DECEMBER 31, 2016		
First Quarter	\$ 43.20	\$ 6.80
Second Quarter	\$ 8.00	\$ 4.59
Third quarter	\$ 18.10	\$ 6.61
Fourth quarter	\$ 32.30	\$ 6.96
YEAR ENDED DECEMBER 31, 2017		
First Quarter	\$ 10.80	\$ 8.05
Second Quarter	\$ 8.68	\$ 5.62
Third Quarter	\$ 6.80	\$ 4.75
Fourth Quarter	\$ 7.59	\$ 3.50
YEAR ENDED DECEMBER 31, 2018		
First Quarter (through February 28, 2018)	\$ 4.29	\$ 2.52

## **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, 2017. In June 2017, our stockholders approved the 2017 Stock Incentive Plan, which provides for a maximum of 500,000 awards. All share numbers in this paragraph and in the following table have been adjusted for the one-for-ten reverse stock split effective January 19, 2018.



### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders			
2009 Stock Incentive Plan	23,998	\$26.07	34,047
2014 Stock Incentive Plan	254,591	\$17.81	29,149
2017 Stock Incentive Plan	10,000	\$ 6.10	490,000
Equity compensation plans not approved by security holders			
Total	288,589	\$18.09	533,196

Subsequent to December 31, 2017, we issued Jeff Wolf, Jeff Hutchins, and Ann Rosar options exercisable for 59,559, 29,647, and 6,618 shares of common stock, respectively, vesting pro rata on a monthly basis over four (4) years as part of their 2017 bonus compensation. Subsequent to December 31, 2017, we also issued: (i) Jeff Wolf 26,072 restricted stock units that vested immediately, but are subject to a one year restriction on transferability, and (ii) Jeff Wolf and Ann Rosar 40,500 and 4,500 restricted stock units, respectively, that vested 25% on the grant date, with the remaining restricted stock units vesting 25% on each of the second, third and fourth anniversary of the grant date.

### Recent Sales of Unregistered Securities

On March 31, June 30, September 30, and December 31, 2017 we issued 11,798, 17,213, 7,692, and 13,158 shares of our common stock, respectively to an investor relations firm, as partial consideration for services rendered pursuant to the terms of an agreement that we entered into with such firm.

These shares were issued upon the exemption from the registration provisions of the Securities Act provided for by Section 4(a)(2) thereof for transactions not involving a public offering. Use of this exemption is based on the following facts:

- Neither we nor any person acting on our behalf solicited any offer to buy nor sell securities by any form of general solicitation or advertising.
- At the time of the purchase, the firm was an accredited investor, as defined in Rule 501(a) of the Securities Act.
- The firm has had access to information regarding our company and is knowledgeable about us and our business affairs.
- Shares of common stock issued to the firm were issued with a restrictive legend and may only be disposed of pursuant to an effective registration or exemption from registration in compliance with federal and state securities laws.

***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, 2017 and December 31, 2016 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, 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 approaches to activate and co-stimulate a patient's immune system against cancer. Our co-stimulatory antibody is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram the immunity and provide a long-term, durable clinical effect. Our T-cell activating platform (TCAP) produces therapies designed to turn immunologically cold tumors hot, and be administered in combination with checkpoint inhibitors and other immuno-modulators to increase clinical effectiveness. Unlike many other patient specific immunotherapy approaches, our drugs are off-the-shelf, which means that we can administer drug immediately without extracting patient material at a substantially lower cost of goods sold. Our TCAP product candidates from our *ImPACT*<sup>®</sup> and *ComPACT* platforms are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. We are currently enrolling patients in our Phase 2 clinical trial for advanced NSCLC, in combination with Bristol-Myers Squibb's nivolumab (Opdiv<sup>®</sup>). We also have numerous pre-clinical programs at various stages of development.

Through our *ImPACT*<sup>®</sup> platform technology our initial TCAP, we have developed product candidates that consist of live, allogeneic *off-the-shelf* genetically-modified, irradiated human cancer cells. These cells secrete a broad spectrum of CTAs, classified functionally as tumor specific neoantigens, together with the gp96 protein. Our *ImPACT*<sup>®</sup> technology achieves this by reprogramming live tumor cells to secrete gp96, to serve as a chaperone for tumor antigens to activate and expand T-cell immunity; thereby, transforming the allogeneic cells into machines that activate a robust killer CD8+ T cell immune attack against a patient's cancer. Unlike autologous or personalized monotherapy approaches that either require the extraction of blood or tumor tissue from each patient or the creation of an individualized treatment, our product candidates are fully allogeneic, and do not require extraction of individual patient's material or custom manufacturing. As a result, our product candidates can be mass-produced and have the ability to be readily available for immediate patient use. Because each patient receives the same treatment, we believe that our immunotherapy approach offers logistical, manufacturing and other cost benefits, compared to patient-specific or precision medicine approaches.

*ComPACT* our second TCAP, is a dual-acting immunotherapy designed to deliver T-cell activation and enhanced, T-cell specific co-stimulation in a single treatment. *ComPACT* helps unlock the body's natural defenses and builds upon *ImPACT*<sup>®</sup> by also providing alternative co-stimulation targeting enhanced T-cell activation and expansion. It has the potential to simplify combination immunotherapy development with enhanced safety for oncology patients, as it is designed to deliver the gp96 heat shock protein with each selected tumor cell line's neoantigens (CTAs) and a T-cell co-stimulatory fusion protein (e.g. OX40L) into a single intradermal treatment. *ComPACT* serves as a booster to expand the number of antigen-specific T-cells compared to co-stimulator alone, while also enhancing the activation of cancer antigen-specific CD8+ memory T-cells for an extended time after treatment. *ComPACT* has the potential to be a cost-effective approach compared to conventional immunotherapies.

Pelican, our subsidiary, is a biotechnology company focused on the development of monoclonal antibody and fusion protein-based therapies designed to activate the immune system. PTX-35, which is currently in 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 the immunity and provide a long-term, durable clinical effect. When combined with immunotherapies, including the *ImPACT*<sup>®</sup> and *ComPACT* platform technologies, PTX-35 has been shown to enhance antigen specific T-cell activation to eliminate tumor cells. PTX-15, Pelican's second product candidate, is a human TL1A-Ig fusion protein designed as a shorter half-life agonist of TNFRSF25.

In June 2016, Pelican was awarded a \$15.2 million CPRIT Grant to support further development of PTX-35 and fund a Phase 1 clinical trial to examine potential benefits to patients with several types of cancers, such as lung, lymphoma, prostate, pancreatic and ovarian.

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

We are devoting substantially all of our resources to developing HS-110, including conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue 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.

## **2017 Developments**

On December 7, 2017, we received written responses from the FDA following a granted Type C meeting regarding the planned registrational HS-110 clinical trial design for the treatment of NSCLC. The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

On October 30, 2017, Pelican received the second tranche in the amount of \$6.5 million of its \$15.2 million CPRIT Grant award. The CPRIT award supports the pre-clinical development, manufacturing and clinical development of a 70-patient Phase 1 clinical trial for PTX-35.

On September 27, 2017, we announced a manufacturing agreement with KBI Biopharma, Inc. a global biopharmaceutical contract development and manufacturing organization, for cGMP product of Pelican's PTX-35 antibody and PTX-15 fusion protein. Under the agreement, KBI Biopharma will offer comprehensive development and manufacturing services, which is expected to offer advantages such as speed, productivity, stability and flexibility over traditional approaches to cell line development.

On June 28, 2017, Pelican reported that it was on track to meet product development milestones and received the first tranche in the amount of approximately \$1.8 million of its \$15.2 million CPRIT Grant award.

On May 1, 2017, we announced the completion of the acquisition of an 80 percent controlling interest in Pelican.

On March 21, 2017, we reported promising interim results for the Phase 1b portion of the trial evaluating HS-110 in combination with Bristol-Myers Squibb's checkpoint inhibitor, nivolumab (Opdiv<sup>®</sup>), for the treatment of advanced NSCLC.

## **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 private placement of our preferred stock, our July 2013 initial public offering in which we received net proceeds of \$24.3 million, our March 2015 public offering in which we received net proceeds of \$11.1 million, our March 2016 public offering 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, and our November 2017 public offering in which we received net proceeds of approximately \$2.4 million. In addition, we received \$7.5 million from our debt facility, which has subsequently been paid back in full as of December 30, 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, 2017. As of December 31, 2017, we have received \$8.3 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. To date, we received net proceeds of approximately \$1.4 million from the sale of shares of our common stock through the H.C. Wainwright Sales Agreement. Our consolidated financial statements for the years ended December 31, 2017 and 2016 have been prepared on a going concern basis. As of December 31, 2017, we had an accumulated deficit of \$68.8 million. We had net losses of \$12.4 million and \$13.0 million for the years ended December 31, 2017 and 2016, 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. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Accordingly, there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under the H.C. Wainwright Sales Agreement 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 revenue generally consists of research funding from our CPRIT Grant and a research funding agreement with Shattuck that terminated on January 31, 2017. 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 \$6.8 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 into revenue 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.

### ***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. The Company uses widely accepted valuation techniques to determine the fair value of its reporting units used in its annual goodwill impairment analysis. The Company s valuation is primarily based on qualitative and quantitative assessments regarding the fair value of the reporting unit relative to its carrying value.

### *Income Tax*

On December 22, 2017, the Tax Cuts and Jobs Act (the Act ) was enacted into law. The Tax Act lowered the Federal corporate tax rate from 34% to 21% for periods beginning on or after January 1, 2018 and made numerous other tax law changes. We have measured deferred tax assets at the enacted tax rate expected to apply when these temporary differences are expected to be realized or settled. We are required to recognize the effect of tax law changes in the period of enactment. Additional federal and state interpretive guidance is still forthcoming that could potentially affect the measurement of these balances or give rise to new deferred tax amounts. As such, the remeasurement of our deferred tax balance is provisional pending future guidance. We reasonably anticipate that any such guidance will be available prior to December 31, 2018.

Further, as part of the acquisition of Pelican, indefinite-lived intangibles were included for in-process R&D. This results in a deferred tax liability as there is no tax basis for these intangibles. Indefinite-lived intangibles are not available to offset deferred tax assets for purposes of determining any needed valuation allowance. Therefore, the valuation allowance was applied only to the definite-lived deferred tax assets and liabilities resulting in a net deferred tax liability position.

### *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 May 2017, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting (ASU 2017-09)*. This ASU provides that an entity should account for the effects of a modification unless the fair value, the vesting conditions of the modified award and the classification of the modified award (equity or liability instrument) are the same as the original award immediately before the modification. The provisions of this ASU are effective for years beginning after December 15, 2017, with early adoption permitted. The Company's early adoption of this standard in the third quarter of 2017 did not have a significant impact to the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment (Topic 350)*. This standard eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. This guidance is effective for interim and annual goodwill impairment tests in fiscal years beginning after December 15, 2019 with early adoption permitted. This guidance must be applied on a prospective basis. The Company chose to adopt this standard beginning in the third quarter of 2017 and the early adoption of this standard did not have a significant impact to the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805)* to clarify the definition of a business, which is fundamental in the determination of whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses combinations. The updated guidance requires that in order to be considered a business the integrated set of assets and activities acquired must include, at a minimum, an input and process that contribute to the ability to create output. If substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar assets, it is not considered a business, and therefore would not be considered a business combination. The update is effective for fiscal years beginning after December 15, 2018, and interim periods with fiscal years beginning after December 15, 2019, with early adoption permitted. The Company has not determined the impact of this standard and does not plan early adoption of this standard.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09)*. Under ASU 2016-09, the tax effects of stock compensation will be recognized as income tax expense or benefit to the Company's income statement and the tax effects of exercised or vested awards will be treated as discrete items in the reporting period in which they occur. Along with other income tax cash flows, excess tax benefits will be classified as operating activities, and cash paid by the Company when directly withholding shares for tax withholding purposes will be classified as financing activities. The Company has elected to continue to account for forfeitures when they occur. The adoption of ASU 2016-09 did not have a material impact to the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, requiring lessees to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and (2) a right-of-use ( ROU ) asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The update is effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2020. The Company currently anticipates that upon adoption of the new standard, ROU assets and lease liabilities will be recognized in amounts that will be immaterial to the consolidated balance sheets.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (ASU 2014-09)*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. The Company has substantially completed its initial review of the CPRIT contract and the related guidance. The CPRIT contract includes reimbursement for qualified expenditures incurred. Grant revenue is recognized as work is performed and qualifying costs are incurred. The Company, based on its initial analysis, does not anticipate a material effect on the timing and measurement of revenue. The Company anticipates using the modified retrospective method of adoption and is currently evaluating the required disclosures.

## **RESULTS OF OPERATIONS**

### ***Year Ended December 31, 2017 and 2016***

#### ***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 three year project.

As of December 31, 2017, we have provided approximately \$1.2 million in matching funding and we have \$6.4 million remaining to provide over the three-year project, with \$2.9 million remaining for the second CPRIT fiscal year (June 2017 through May 2018) of the award, and \$3.5 million for the third CPRIT fiscal year (June 2018 through May 2019).

As of December 31, 2017, CPRIT has provided \$8.3 million of the total \$15.2 million grant. The remaining \$6.9 million will become available in the third CPRIT fiscal year (June 2018 through May 2019).

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 \$1.5 million for the year ended December 31, 2017 for qualified expenditures under the grant. We recognized no grant revenue related to CPRIT during the year ended December 31, 2016. As of December 31, 2017, we had deferred revenue of \$7.0 million for proceeds received but for which the costs had not been incurred or the conditions of the award had not been met.

We also recognized research funding revenue of approximately \$0.02 million for research and development services, which included labor and supplies, provided to Shattuck Labs, Inc. ( Shattuck ) which research funding agreement ended January 31, 2017. We recognized \$0.3 million of research funding revenue for research and development services, provided to Shattuck for year ended December 31, 2016. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.



### *Operating Expenses*

Total operating expenses for the year ended December 31, 2017 increased 10.4% to \$14.9 million compared to \$13.5 million for the year ended December 31, 2016. For the year ended December 31, 2017 operating expenses are primarily comprised of research and development, and general and administrative expenses, as well as change in the fair value of contingent consideration due to the Company's acquisition of an 80% controlling interest in Pelican during the year. Research and development expenses were \$8.3 million, general and administrative expenses were \$6.4 million and the change in fair value of contingent consideration was \$0.2 million for the year ended December 31, 2017 as compared to research and development expenses of \$9.3 million and general and administrative expenses of approximately \$4.1 million for the year ended December 31, 2016. There was no contingent consideration in 2016. For the year ended December 31, 2017, research and development expenses represented approximately 56% of operating expenses, general and administrative expenses represented approximately 43% and change in fair value of contingent consideration 1% of operating expenses. For the year ended December 31, 2016, research and development expenses represented approximately 69% of operating expenses and general and administrative expenses represented approximately 31% of operating expenses.

### *Research and development expense*

Research and development expenses decreased by 10.8% to \$8.3 million for the year ended December 31, 2017 compared to \$9.3 million for the year ended December 31, 2016 as we have focused our resources primarily on our NSCLC trial. The \$1.0 million decrease resulted from the following:

HS-410 expense decreased \$2.3 million due to the current phase of the trial in which patients are in long-term follow-up for recurrence-free survival. HS-130, *ComPACT*<sup>™</sup> decreased \$0.2 million due to reductions in CMC activities. These decreases were offset by the increased expense of \$1.1 million for HS-110 primarily attributable to CMC activities, as well as continued patient enrollment as we advance into Phase 2 of our multi-arm trial. Other programs increased \$0.1 million and include preclinical costs associated with our Zika program, T-cell costimulatory programs, and laboratory supplies.

Unallocated expenses include personnel-related expenses, professional and consulting fees, and travel and other costs. These costs increased approximately \$0.3 million primarily related to the increase in consultant fees and travel and other costs offset by a decrease in personnel costs.

The following table sets forth our research and development expenses related to our programs for the years ended December 31, 2017 and 2016.

<b>Programs</b>	<b>Year ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
	(in thousands)	
HS-410	\$ 725	\$ 3,073
HS-110	2,566	1,491
HS-130	164	319
Other programs	754	663
Unallocated research and development expenses	4,059	3,785
Total research and development expenses	\$ 8,268	\$ 9,331

*General and administrative expense*

General and administrative expense increased approximately 56.1% to \$6.4 million for the year ended December 31, 2017 compared to \$4.1 million for the year ended December 31, 2016. The \$2.3 million increase is primarily attributable to \$1.3 million increase in professional services, consultants and other third-party expenses, as well as approximately \$0.6 million in acquisition costs, and \$0.4 million increase in personnel and related expenses primarily related to the acquisition of Pelican.

*Interest income*

Interest income decreased for the year ended December 31, 2017 as compared to the year ended December 31, 2016. The decrease is due to the Company's decreased investment balance during the year ended December 31, 2017.

*Other income*

Other income was \$0.1 million for the year ended December 31, 2017 as compared to \$0.7 million for the year ended December 31, 2016. Other income is primarily related to the R&D Tax Incentive for expenses associated with clinical trial activities conducted in Australia. Other income decreased \$0.6 million as we initiated the closure of the HS110 lung cancer trial in Australia that was under the Australian R&D tax protocol.

*Interest expense*

Interest expense for the year ended December 31, 2017 was \$0 compared to \$0.6 million for the year ended December 31, 2016. The interest expense for the year ended December 31, 2016, was attributable to the bank loan which was repaid in total as of the year ended December 31, 2016.

*Net loss attributable to Heat Biologics, Inc.*

We had a net loss attributable to Heat Biologics, Inc. of \$11.8 million, or (\$3.08) per basic and diluted share for the year ended December 31, 2017 compared to a net loss of \$12.6 million, or (\$7.15) per basic and diluted share for the year ended December 31, 2016.

**BALANCE SHEET AS OF DECEMBER 31, 2017 AND 2016**

*Prepaid Expenses and Other Current Assets.* Prepaid expenses and other current assets was approximately \$2.0 million as of December 31, 2017 and \$0.3 million as of December 31, 2016. The \$1.7 million increase was attributable to the amount paid in advance for cGMP production of our PTX-35 antibody and PTX-15 fusion protein, as well as an increase in in the amount paid in advance for CMC material as we progress our clinical trial studies for HS-110.

*In-Process R&D and Goodwill.* As of December 31, 2017, the Company recorded in-process R&D of \$5.9 million and goodwill of \$2.2 million from its acquisition of Pelican Therapeutics, Inc. The Company had no in-process R&D nor goodwill as of December 31, 2016.

*Accounts Payable.* Accounts payable was approximately \$1.0 million as of December 31, 2017 compared to approximately \$0.3 million as of December 31, 2016. The increase of approximately \$0.7 million was related to payables for CMC and clinical trial activities and for our R&D programs, as well as increase in payables associated with our Pelican subsidiary.

*Deferred Revenue.* As of December 31, 2017, we had deferred revenue of \$7.0 million for 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 no deferred revenue as of December 31, 2016.

*Accrued Expenses and Other Liabilities.* Accrued expenses were approximately \$2.3 million as of December 31, 2017 compared to approximately \$1.3 million as of December 31, 2016. The increase of approximately \$1.0 million was primarily related to the increased clinical trial activity in 2017.

*Other Long-Term Liabilities.* Other long term liabilities were \$0.2 million as of December 31, 2017 and \$0.5 million as of December 31, 2016. The \$0.3 million decrease was attributable to the complete reclassification to current liabilities of the percentage of investigator site fees that are held back until a clinical study is complete.

*Deferred Tax Liability.* As of December 31, 2017, we had deferred tax liability of \$1.3 million related to its acquisition and is recorded on our consolidated balance sheets. The deferred tax liability was determined using enacted tax rates in effect as of the time of the acquisition. We had no deferred tax liability as of December 31, 2016.

*Contingent Consideration.* As of December 31, 2017, we had contingent consideration of \$2.6 million 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 as of December 31, 2017, we determined the change in the estimated fair value of the contingent consideration from the date of acquisition to be approximately \$0.2 million due to the effect of the change in discount rate and passage of time on the fair value measurement. We had no contingent consideration as of December 31, 2016.

## LIQUIDITY AND CAPITAL RESOURCES

### Sources of liquidity

All share numbers in the discussion below and in the following tables have been adjusted for the one-for-ten reverse stock split effective January 19, 2018.

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, our July 2013 initial public offering in which we received net proceeds of \$24.3 million, our March 2015 public offering in which we received net proceeds of \$11.1 million, our March 2016 public offering of 910,000 shares of our common stock and warrants to purchase up to an aggregate of 682,500 shares of our common stock at a combined price of \$7.50 per share for net proceeds of \$6.1 million, an additional \$3.9 million from the exercise of 386,343 warrants, our March 2017 public offering of 575,000 shares of our common stock at a price to the public of \$8.00 per share for net proceeds of approximately \$4.1 million, and our November 2017 public offering of 581,395 shares of our common stock and additional issuance of 39,255 shares of our common stock at a price to the public of \$4.30 per share for net proceeds of approximately \$2.4 million after deducting underwriting discounts and commissions and other estimated offering expenses. In addition, we received \$7.5 million from our debt facility which was been paid back in full as of December 30, 2016 and we have received \$9.3 million of net proceeds from sales through the At Market Issuance Sales Agreement (the FBR Sales Agreement ) with FBR Capital Markets & Co. through December 31, 2017. As of December 31, 2017, we have received \$8.3 million in grant funding from CPRIT Grant through Pelican. On January 18, 2018, we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC to replace the FBR Sales Agreement. To date, we have received net proceeds of approximately \$1.4 million from the sale of shares of our common stock through the HCW Sales Agreement. Our consolidated financial statements for the years ended December 31, 2017 and 2016 have been prepared on a going concern basis. As of December 31, 2017, we had an accumulated deficit of \$68.8 million. We had net losses of \$12.4 million and \$13.0 million for the years ended December 31, 2017 and 2016, respectively.

We believe that our existing cash and cash equivalents will not be sufficient to meet our anticipated cash needs for the next twelve months. We intend to spend substantial amounts on research and development and clinical and regulatory activities, including product development, regulatory and compliance, preclinical and clinical studies in support of our future product offerings, and the enhancement and protection of our intellectual property. We will need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. Due to our Pelican Acquisition, we will be required to devote additional funds to Pelican. The CPRIT Grant requires that Pelican provide matching funds for one half of the award amount in order for Pelican to receive the grant funding. In order to receive the full \$15.2 million award over three years, Pelican must raise matching funds in the aggregate amount of approximately \$7.6 million. As of December 31, 2017, we have loaned Pelican approximately \$1.2 million in matching funds.

To meet our financing needs, we are considering multiple alternatives, including, but not limited to, current and additional equity financings, which we expect will include sales of common stock through the H.C. Wainwright Sales Agreement, debt financings and/or funding from partnerships or collaborations. There can be no assurance that we will be able to meet the requirements for use of the H.C. Wainwright Sales Agreement, especially in light of the fact that we are subject to the smaller reporting company requirements and rules of the NASDAQ Capital Market, or to complete any such transactions on acceptable terms or otherwise. Even if we meet the requirements to use the H.C. Wainwright Sales Agreement, we may not raise enough money through the use of the H.C. Wainwright Sales Agreement and may sell securities through any one of the methods mentioned above at various times or at the same time as we use the H.C. Wainwright Sales Agreement. If we are unable to obtain the necessary capital, we will scale back our operations, license or sell our assets, seek to be acquired by another entity and/or cease operations. We are continually evaluating various cost-saving measures in light of our cash requirements in order to focus our resources on our product candidates. We may take additional action to reduce our immediate cash expenditures, including re-visiting our headcount, offering vendors equity in lieu of the cash due to them and otherwise limiting our other research expenses, in order to direct our resources primarily to advance the Phase 2 trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC) and develop the PTX programs. As of December 31, 2017, we had approximately \$9.8 million in cash and cash equivalents.

## **Cash flows**

*Operating activities.* The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The significant decrease in cash used in operating activities for the year ended December 31, 2017 compared to the year ended December 31, 2016 was due to the funding associated with our CPRIT Grant as well as working capital adjustments.

*Investing activities.* Cash used in investing activities during the year 2017 included the purchase of Pelican Therapeutics net of cash acquired and purchases of property and equipment. Cash provided by investing activities during the year 2016 included the proceeds from maturities of various short-term investments offset by purchases of these investments and purchases of property and equipment. During the year ended December 31, 2016 we sold our remaining short-term investments and no longer holds debt securities.

*Financing activities.* Cash provided by financing activities during the year ended December 31, 2017 was primarily from the March 2017 public offering which generated net proceeds of approximately \$4.1 million, \$2.3 million net proceeds from the FBR Sales Agreement, and net proceeds of approximately \$2.4 million after deducting underwriting discounts and commissions and other estimated offering expenses from our November 2017 public offering. Cash provided by financing activities during the year ended December 31, 2016 was from the March 2016 public offering and subsequent exercise of 3,863,429 warrants which generated net proceeds of approximately \$10.0 million (after deduction of offering expenses), as well as approximately \$6.8 million in net proceeds (after deduction of offering expenses) from sales through the FBR Sales Agreement during 2016. These inflows of cash were offset by payments of \$6.9 million to Square 1 Bank to repay in full our outstanding loan.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

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

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

We have incurred an accumulated deficit of \$68.8 million through December 31, 2017. We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

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

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

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the progress of our research activities;

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the number and scope of our research programs;

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the progress of our preclinical and clinical development activities;

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

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

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our ability to achieve our milestones under licensing arrangements;

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

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the costs and timing of regulatory approvals; and

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profitability of our clinical laboratory diagnostic and microbiology services business.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity 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 Agreement Obligations

Under the Purchase Agreement that was entered into in connection with the Pelican Acquisition agreement, we are obligated to make future payments based on the achievement of certain clinical and commercialization milestones. The below milestone payments assume Pelican's achievements of dosing of the first patient in its first Phase 1 trial for an oncology indication in 2019; dosing of the first patient in its first Phase 2 trial for an oncology indication in 2020; successful outcome of the first Phase 2 trial for an oncology indication and dosing of the first patient in its first Phase 3 trial for an oncology indication in 2021; and dosing of the first patient in its first Phase 3 trial for a non- oncology indication in 2022. 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.

Our principal property is our corporate headquarters located in Durham, NC. We lease this space (5,979 square feet) under a lease agreement that has a term that runs through September 30, 2019. Pelican entered into a five-year lease for a total of 5,156 square feet in San Antonio, Texas. The Company anticipates Pelican's occupancy by March 31, 2018.

Below is a table of our contractual obligations for the years 2018 through 2022 as of December 31, 2017 (in thousands).

	2018	2019	2020	2021	2022	Total
License agreements	\$ 64	\$ 74	\$ 103	\$ 228	\$ 784	1,253
Lease agreements	325	310	116	118	120	989
Total	\$ 389	\$ 384	\$ 219	\$ 346	\$ 904	2,242

## 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-28.

**Item 9.**

***Changes In and Disagreements with Accountants on Accounting and Financial Disclosures***

None.

**Item 9A.**

***Controls and Procedures***

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Vice President of Finance, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. We have adopted and maintain disclosure controls and procedures (as defined Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company's 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. During the course of the year, we identified a material weakness in our controls relating to accounting for significant transactions, as described below. Based on our evaluation of our disclosure controls and procedures as of the end of the period covered by this report, on the implementation of additional processes to address accounting for and financial statement presentation of significant transactions and our additional internal review processes to ensure appropriate accounting and disclosure of significant transactions, our Chief Executive Officer and Vice President of Finance concluded that our material weakness was remediated and our disclosure controls and procedures were effective at a level that provides reasonable assurance as of the last day of the period covered by this report.

**Changes in Internal Control over Financial Reporting**

We have remediated the material weakness in our internal controls with respect to the purchase price accounting for the acquisition that occurred during the second quarter of 2017. We implemented the following steps to improve the overall processes of identifying and reviewing purchase accounting considerations beyond the recording of the initial purchase price by adding additional considerations to our processes to address the accounting for and financial

statement presentation of activities that occur beyond the initial purchase accounting and subsequent adjustments to purchase accounting; and performing additional internal review processes to ensure the appropriate accounting and disclosure of significant transactions.

No other 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) occurred during our fiscal year ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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

**Item 9B.**

***Other Information***

None.

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

Below is certain information regarding our directors and executive officers.

<b>Name</b>	<b>Age</b>	<b>Position</b>	<b>Served as an Officer or Director Since</b>
Jeffrey Wolf	54	Chairman of the Board of Directors, Chief Executive Officer and President	2008
Jeff T. Hutchins, Ph.D.	59	Chief Scientific Officer and Chief Operating Officer	2017
Ann A. Rosar	65	Vice President of Finance, Controller and Secretary	2016
John Monahan, Ph.D.	71	Director	2009
John K.A. Prendergast, Ph.D.	63	Director	2016
Edward B. Smith, III	42	Director	2009

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

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

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

Ms. Rosar joined our company as Controller in January 2015 and in April 2016 was named our Vice President of Finance, Controller and Secretary. Ms. Rosar has over twenty years of experience in finance with publicly held companies and more than fifteen years of experience regarding regulatory reporting requirements. Prior to serving as our Controller, Ms. Rosar served as Manager of Financial Reporting and Accounting for LipoScience, Inc. (acquired by LabCorp), a provider of specialized cardiovascular diagnostic tests, from 2013 to 2015. From 2007 until 2013 she served in various roles at DARA Biosciences, Inc. (now Midatech Pharma US), an oncology supportive care pharmaceutical company, including as the Vice President of Finance, Chief Accounting Officer and Controller. Ms. Rosar was the Manager of Financial Reporting and Accounting with Cicero, Inc. (formerly Level 8 Systems), a provider of business integration software, from June 2000 until November 2007, where she was responsible for Securities and Exchange Commission reporting, audits and budget analysis. Prior to that position, she served as Senior Financial Analyst-Business Operations for Nextel Communications.

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

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

Dr. Monahan has served on our Board since November 2009 and is currently a consultant to Synthetic Biologics, Inc., a clinical stage company developing therapeutics to protect the gut microbiome (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. Dr. Prendergast is a director and executive chairman of the board of directors of Antyra, Inc., a privately-held biopharmaceutical firm. He was previously a member of the board of the life science companies AVAX Technologies, Inc., Avigen, Inc. and MediciNova, Inc. From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr. Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

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

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

Mr. Smith has served on our Board since November 2010. Since January 1, 2015, Mr. Smith has also been Managing Member of Aristar Capital Management, LLC, a New York-based investment firm founded in 2015. From 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.

<b>Board Members</b>	<b>Audit Committee</b>	<b>Compensation Committee</b>	<b>Nominating and Governance Committee</b>
Jeff Wolf			
John Monahan, Ph.D.	Member	Chairman	Member
Edward Smith	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](http://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](http://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, 2017, 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:

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recommending to the Board of Directors individuals for appointment to vacancies on any committee of the Board of Directors;

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recommending to the Board of Directors regarding any changes to the size of the Board of Directors or any committee;

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reporting to the Board of Directors on a regular basis; and

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performing any other duties or responsibilities expressly delegated to the committee by the Board of Directors relating to board or committee members.



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

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

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

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

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confers with the Chairman of the Board regarding Board meeting agenda;

.  
chairs meetings of the independent directors including, where appropriate, setting the agenda and briefing the Chairman of the Board on issues discussed during the meeting;

.  
oversees the annual performance evaluation of the CEO;

.  
consults with the Nominating and Governance Committee and the Chairman of the Board regarding assignment of Board members to various committees; and

.  
performs such other functions as the Board may require.

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



***Risk Oversight***

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

**Code of Conduct**

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

**2017 Director Compensation****Compensation of Directors**

The following table sets forth information for the fiscal year ended December 31, 2017 regarding the compensation of our directors who at December 31, 2017 were not also named executive officers.

<b>Name and Principal Position</b>	<b>Fees Earned or Paid in Cash</b>	<b>Option Awards</b>	<b>Other Compensation</b>	<b>Totals</b>
John Monahan, PhD (1)	\$ 86,667	\$ 53,550		\$140,217

John K. A. Prendergast, PhD (2)	\$242,167	\$107,100	\$349,267
Edward Smith (1)	\$ 77,500	\$ 53,550	\$131,050

(1)

The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to purchase 90,000 shares of common stock (9,000 post-split shares) granted on January 3, 2017 to Dr. Monahan and Mr. Smith with 100% of these options vesting on the one year anniversary of the date of the grant, subject to remaining on the Board of Directors. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 8 to the Company's audited consolidated financial statements for the years ended December 31, 2017 and 2016.

(2)

The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to purchase 180,000 shares of common stock (18,000 post-split shares) granted on January 3, 2017 to Dr. Prendergast as lead independent director with 100% of these options vesting on the one year anniversary of the date of the grant, subject to remaining on the Board of Directors. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 8 to the Company's audited consolidated financial statements for the years ended December 31, 2017 and 2016.

As of December 31, 2017, 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, as adjusted for the one-for-ten reverse stock split effective January 19, 2017:

<b>Name</b>	<b>Aggregate Number of Option Awards</b>
John Monahan, Ph.D.	15,486
John K. A. Prendergast, Ph.D.	22,000
Edward Smith	14,725

Our Compensation Committee conducted an evaluation of the compensation of the members of our board of directors with assistance from Korn Ferry Hay Group ( Hay Group ). As described in additional detail below under Item 11.

Executive Compensation, Hay Group 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 Hay Group 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 2017, and anticipated to remain the same for the current year, directors who are not employees receive an annual cash fee of \$35,000 as well as a cash fee of \$8,000 for service on the Audit Committee and \$5,000 for service on each of the Compensation 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.

On January 8, 2018, Dr. Monahan and Mr. Smith received an option grant each to purchase 9,530 shares of our common stock (having a value of \$25,634) vesting on the one year anniversary of the grant date and for his services as lead independent director Dr. Prendergast received an option grant to purchase 19,059 shares of common stock (having a value of \$51,268).

In addition, on January 2, 2017, our non-executive directors, Dr. Monahan and Mr. Smith were each granted an option to purchase 90,000 shares of our common stock (which is 9,000 shares on a split adjusted basis), and for services as lead independent director Dr. Prendergast was granted an option to purchase 180,000 shares of our common stock (which is 18,000 shares on a split adjusted basis). The stock options were granted with an exercise price of \$0.87 per share (which is \$8.70 on a split adjusted basis), vested in full on January 2, 2018 and expire ten (10) years from the date of the grant, unless terminated earlier.

## **Item 11.**

### ***Executive Compensation***

#### **NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE**

All share numbers in the discussion below and in the following tables have been adjusted for the one-for-ten reverse stock split effective January 19, 2018.

## 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 believes that executives' interests should be aligned with those of the stockholders. Executives are granted stock options so that their total compensation is tied directly to the same value realized by our stockholders. Executive bonuses are tied directly to the value that we gain from an executive's contribution to our success as a whole.

*Compensation is Competitive* — The Compensation Committee seeks 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. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable given our level of performance and other 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, long-term and strategic 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:

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a base salary;

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

.

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 (as defined below), which includes the following information:

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

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the value of all outstanding equity awards; and

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the Compensation Committee also meets with our Chairman, Chief Executive Officer and other senior management in connection with compensation matters, and may retain and meet in executive session with, compensation 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 (i) Jeff Wolf, our Chief Executive Officer, (ii) Ann Rosar, our Vice President of Finance, and (iii) Jeff Hutchins, our Chief Scientific Officer and Chief Operating Officer (collectively, our Named Executive Officers ), is reasonable and competitive. 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 Board members (including retainer, committee and committee chair's fees, stock options and other similar items 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; (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](http://www.heatbio.com).

### *Use of Compensation Consultant*

As noted above, the Compensation Committee retained Hay Group, a nationally-recognized global human resources consulting firm, as its independent compensation advisor for 2017. Hay Group 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. Hay Group reports to the Chairman of the Compensation Committee and has direct access to the other members of the Compensation Committee. Hay Group does not provide any other services to the Company other than in its role as the Compensation Committee's independent advisor.



## **Competitive Considerations**

In making compensation decisions with respect to each element of compensation for our Named Executive Officers, the Compensation Committee considers the competitive market pay data from both other similarly situated public companies and a premier compensation survey which is specific to our size and industry.

The Compensation Committee generally targets total executive compensation within a competitive range of market median (+/- 15% of median) for executives in similar positions and with similar responsibilities and experience at similarly-situated 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.

### ***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.

### **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 of the study data provide to us by Hay Group and other comparative research performed by the Committee, the Committee was able to compare the compensation for the Chief Executive Officer, Vice President of Finance and Chief Scientific Officer/ Chief Operating Officer, including base salary, long-term incentives and bonuses. It was determined that our Chief Executive s Officer s and Chief Scientific Officer s/ Chief Operating Officer s salary were within a competitive range of market relative to similarly situated positions of similar companies. It was determined that due to the fact that we do not have a Chief Financial Officer that the Vice President of Finance assumes many of the responsibilities of a Chief Financial Officer and therefore based upon her added responsibilities, the Vice President of Finance s base salary was slightly below the competitive range of market relative to similarly situated positions of similar companies and therefore, the base salary for our Vice President of Finance was increased to \$260,000 in January 2018, to keep her salary competitive with those of similarly situated executives in the peer group. The current base salaries for our Named Executive Officers are:

<b>Named Executive Officer</b>	<b>Base Salary</b>
Jeff Wolf, Chief Executive Officer	\$417,150
Ann Rosar, Vice President of Finance	\$260,000
Jeff Hutchins, Chief Scientific Officer and Chief Operating Officer	\$335,000

## 2. Bonuses

The Compensation Committee also makes recommendations to the full Board of Directors for determining bonuses. The Compensation Committee also used information from the report and analysis discussed above in determining bonuses as well as its own research of peer company compensation. For the year ended December 31, 2017, the Compensation Committee approved a \$208,575 cash bonus for Jeff Wolf (50% of pro-rated gross base salary), a \$77,361 cash bonus for Jeff Hutchins (25% of pro-rated gross base salary) and a \$53,125 cash bonus for Ann Rosar (25% of pro-rated gross base salary). Mr. Wolf agreed to accept 26,072 restricted stock units in lieu of \$52,144 of his 2017 cash bonus (25% of his cash bonus). The restricted stock units received in lieu of the cash bonus had a value at the time of grant of \$104,288. Each restricted stock units represents a contingent right to receive one share of common stock.

The employment agreement with each of Jeff Wolf and Jeff Hutchins that was in effect during 2017 provided that each was eligible for a cash performance bonus of up to fifty percent and twenty five percent, respectively of each of their 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. Ann Rosar's employment agreement provides that she is eligible for an annual bonus, payable in cash and/or equity, in the discretion of the board of directors. The bonuses are to be rewarded based on whether, in the discretion of the Compensation Committee and the board of directors, our company and the Named Executive Officer met certain objectives established by the Compensation Committee. 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 Compensation Committee has elected to grant stock options to the Named Executive Officers and other key employees as the primary long-term incentive vehicle. In making this determination, the Compensation Committee considered a number of factors including: the accounting impact, potential value of stock option grants versus other equity instruments and cash incentives, and the alignment of equity participants with stockholders. The Compensation Committee determined to grant stock options to:

- enhance the link between the creation of stockholder value and executive compensation;

- provide an opportunity for equity ownership;
- act as a retention tool; and
- provide competitive levels of total compensation.

Each of Jeff Wolf, Jeff Hutchins and Ann Rosar were granted options exercisable for 59,999, 29,647 and 6,618 shares of common stock, respectively, as part of their bonus for the year ended December 31, 2017. In addition, Jeff Wolf and Ann Rosar were issued 66,572 and 4,500 restricted stock units, respectively in January 2018. The stock options granted vest in equal monthly installments over a four-year term and are subject to the recipient's continued employment, therefore acting as a significant retention incentive. Of the 66,572 restricted stock units granted to Jeff Wolf, 26,072 were issued to Mr. Wolf, at his option, in lieu of a part of his cash bonus and vested immediately but may not be sold for a one year period from the grant date. The remaining restricted stock units vested 25% on the grant date with the remaining units vesting on the second, third and fourth anniversary of the date of grant.

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.

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.

Set forth below is the compensation paid or accrued to our named executive officers during the years ended December 31, 2017 and December 31, 2016 that exceeded \$100,000.

*Summary Compensation Table*

Name and Principal Position	Year	Salary	Bonus	Stock Awards (7)	Options (7)	Other	Total
Jeffrey Wolf <i>Chairman and Chief Executive Officer</i>	2017	\$ 417,150	\$ 208,575(1)	\$ 213,038(2)	\$ 125,000		\$ 963,763
	2016	\$ 404,583	\$ 202,500(3)	\$ 64,500	\$ 198,396		\$ 869,979
Jeff T. Hutchins <i>Chief Scientific Officer and Chief Operating officer</i>	2017	\$ 309,442	\$ 77,361(4)		\$ 94,583	\$ 66,000(5)	\$ 547,386
Ann A. Rosar <i>Vice President of Finance</i>	2017	\$ 212,500	\$ 53,125(4)	\$ 60,900	\$ 52,975		\$ 379,500
	2016	\$ 152,386	\$ 40,000(3)		\$ 18,834	\$ 40,000(6)	\$ 251,220

(1)

Mr. Wolf agreed to accept 26,072 restricted stock units in lieu of \$52,144 of his cash bonus (25% of his cash bonus). The restricted stock units received in lieu of the cash bonus had a value at the time of grant of \$104,288.

(2)

Includes the value of the restricted stock units (\$52,144) that exceed the value of the bonus foregone. The restricted stock units vest immediately but may not be sold until the one year anniversary of their grant date. Each restricted stock units represents a contingent right to receive one share of common stock.

(3)

This bonus was accrued in 2016 and paid in 2017.

(4)

This bonus was accrued in 2017 and paid in 2018.

(5)

This is the sign-on bonus per Dr. Hutchins' January 2017 employment agreement.

(6)

Represents payment for 2016 Retention bonus paid in 2017.

(7)

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 8 to the Company's audited consolidated financial statements for the years ended December 31, 2017 and 2016.

*Outstanding Equity Awards at Fiscal Year-End (December 31, 2017)*

Name and Principal Position	Option Awards				Stock Awards	
	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 <i>Chairman and Chief Executive Officer</i>	1,097(1)		\$ 23.00	12/18/2019		
	10,000(2)		\$ 86.20	6/11/2024		
	938(3)	313	\$ 45.30	1/12/2025		
	4,703(4)	4,703	\$ 24.70	1/11/2026		
	1,719(5)	5,782	\$ 8.60	12/30/2026	3,750(6)	\$ 14,250
	2,865(7)	9,636	\$ 8.70	1/03/2027	9,375(8)	\$ 35,625
Jeff T. Hutchins <i>Chief Scientific</i>	4,583(9)	15,417	\$ 8.70	1/03/2017		
	1,459(10)	8,542	\$ 6.60	6/28/2027		

*Officer  
and  
Chief  
Operating  
Officer*

Ann A. Rosar	729(11)	271	\$	45.30	1/12/2025		
<i>Vice President of Finance, Controller and Secretary</i>	309(12)	309	\$	24.70	1/11/2026		
	875(13)	1,125	\$	6.60	4/5/2026		
	1,604(14)	5,396	\$	8.70	1/03/2017	5,250(15)	\$ 19,950
	364(16)	2,136	\$	6.60	6/28/2027		

(1)

All shares are fully vested as of December 2013.

(2)

All shares as full vested as of January 2016.

(3)

Issued on January 12, 2015, these options vest over a four-year period and will be fully vested in December 2018.

(4)

Issued on January 11, 2016, these options vest over a four-year period and will be fully vested in December 2019.

(5)

Issued on December 30, 2016, these options vest over a four-year period and will be fully vested in January 2020.

(6)

Issued on December 30, 2016, 3,750 restricted stock units vested as of December 30, 2017; 1,875 will vest December 30, 2018; and 1,875 will vest December 30, 2019. Amount represents the value of shares at December 29, 2017.

(7)

Issued on January 3, 2017, these shares vest over a 46-month period and will be fully vested in January 2021.

(8)

Issued on January 3, 2017, 3,125 restricted stock units vested January 3, 2017; 3,125 will vest January 3, 2018; 3,125 will vest January 3, 2019; and 3,125 will vest January 3, 2019. Amount represents the value of shares at December 29, 2017.

(9)

Issued on January 3, 2017, these shares vest over a 46-month period and will be fully vested in January 2021.

(10)

Issued on June 28, 2017, these shares vest over a 46-month period and will be fully vested in May 2021.

(11)

Issued January 12, 2015, these shares vest over a four-year period and will be fully vested in January 2019.

(12)

Issued on January 11, 2016, these options vest over a four-year period and will be fully vested in January 2019.

(13)

Issued on April 5, 2016, these options vest over a four-year period and will be fully vested in March 2020.

(14)

Issued on January 3, 2017, these shares vest over a 46-month period and will be fully vested in January 2021.



(15)

Issued on January 3, 2017, 1,750 restricted stock units vested January 3, 2017; 1,750 will vest January 3, 2018; 1,750 will vest January 3, 2019; and 1,750 will vest January 3, 2019. Amount represents the value of shares at December 29, 2017.

(16)

Issued on June 28, 2017, these shares vest over a 46-month period and will be fully vested in May 2021.

The chart above does not include the grant on January 8, 2018 of (i) options exercisable for 59,559, 29,647, and 6,618 shares of common stock issued to each of Mr. Wolf, Dr. Hutchins, and Mrs. Rosar, respectively; and (ii) 40,500 and 4,500 restricted stock units that were issued to Mr. Wolf and Ms. Rosar, respectively, which vest 25% on grant date, and 25% on each anniversary of grant date thereafter; and (iii) 26,072 restricted stock units were issued to Mr. Wolf in lieu of \$52,144 of his cash bonus (25% of his cash bonus), which had a value at the time of grant of \$104,288 and vest immediately but may not be sold until the one year anniversary of their grant date.

## **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 and January 1, 2017. Mr. Wolf receives an annual base salary of \$417,150 per year. He also may receive, at the sole discretion of the board, an additional cash performance-based bonuses equal to up to 50% of his then outstanding base salary at the end of each year and a discretionary equity award, with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. Upon execution of the agreement, Mr. Wolf was issued options exercisable for 119,661 shares of our common stock. In addition, he is to receive certain options to purchase 2% of our fully diluted equity at an exercise price equal to the then current market price if our stock is traded on a nationally recognized exchange or NASDAQ and our market capitalization is at least \$250 million for at least 5 days. If Mr. Wolf's employment contract is terminated for death or disability (as defined in the agreement), he (or his estate in the event of death) will receive six month's severance. If Mr. Wolf's employment is terminated by us other than for cause, he will receive 12 month's severance. In addition, if Mr. Wolf's employment is terminated by us other than for cause all Restricted Shares, common stock and options to purchase common stock that would have vested shall immediately vest. Mr. Wolf will not be entitled to any additional severance in the event he is terminated for cause or voluntarily resigns. Under his employment agreement, Mr. Wolf has also agreed to non-competition provisions.

On January 2, 2017, we approved the entry into a four-year employment agreement, effective as of January 1, 2017, with Jeff T. Hutchins, Ph.D., which agreement was amended on June 29, 2017 and January 1, 2018 (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 \$335,000 and will be eligible for a cash performance bonus equal to approximately 25% 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. Additionally, in connection with the execution of the initial Hutchins Employment Agreement, we granted Dr. Hutchins an option to purchase 200,000 shares of our common stock (20,000 shares on a split-adjusted basis), with an exercise price equal to \$0.87 per share (or \$8.70 per share on a split-adjusted basis). These options will vest pro rata, on a monthly basis, over forty-eight months.

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

On April 5, 2016, we entered into a four-year employment agreement with Ann Rosar to serve as our Vice President of Finance, Controller and Corporate Secretary, which 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 receives an annual base salary of \$260,000 and is eligible for a discretionary performance bonus. Additionally, in connection with the execution of the initial Rosar Employment Agreement, we granted Ms. Rosar was a ten-year option exercisable for 20,000 shares of our common stock (which is 2,000 shares on a split-adjusted basis), vesting pro rata on a monthly basis over a four year period. In addition, if Ms. Rosar's employment is terminated for any reason, she or her estate as the case may be, are entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by her to the extent not previously paid (Rosar Accrued Obligations); provided, however, that if her employment is terminated by the Company without Just Cause (as defined in the employment agreement) or by Ms. Rosar for Good Reason (defined as a material breach of the terms of the employment agreement by us, which breach is not cured within thirty (30) days) then in addition to paying the Accrued Obligations, we will continue to pay her then current base salary for a period of four (4) months.

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

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

contained additional provisions that are customary for agreements of this type, including confidentiality, non-competition and non-solicitation provisions

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

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

## **Section 16(a) Beneficial Ownership Reporting Compliance**

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

Based solely on a review of the copies of such forms that were received by us, or written representations from certain reporting persons that no 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, 2017.

## **Code of Ethics**

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

## **Item 12.**

### ***Security Ownership of Certain Beneficial Owners***

The following table sets forth information, as of February 28, 2018, 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 February 28, 2018, we had 4,756,069 shares of common stock outstanding.

### **Principal Stockholders Table**

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 801 Capitola Drive, Suite 12, Durham, North Carolina 27713. Except as otherwise indicated, and subject to applicable community property laws, except to the extent authority is shared by both spouses under applicable law, the Company believes the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Total			Percentage Ownership
	Common Stock	Shares subject to Options (1)	Number of Shares Beneficially Owned	
<b>Executive Officers &amp; Directors</b>				
Jeff T. Hutchins (Chief Scientific Officer and Chief Operating Officer)		11,427	11,427	*
John Monahan, Ph.D. (Director)	517	15,499	16,016	*
John K. A. Prendergast, Ph.D. (Director)		20,083	20,083	*
Ann A. Rosar (Vice President of Finance, Controller and Secretary)	3,949	5,669	9,618	*
Edward Smith (Director) (2)	104,306	14,736	119,042	2.5%
Jeffrey Wolf (Chairman of the Board of Directors, Chief Executive Officer and President) (3)	194,989	29,035	224,024	4.7%
All Executive Officers and Directors, as a group (6 persons)	303,761	96,449	400,210	8.2%
<b>5% Stockholders</b>				
Sabby Management, LLC and affiliates (4)	261,512		261,512	5.5%

\* 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 February 28, 2018.

(2)

Information obtained from a Schedule 13D/A filed on February 14, 2017 with the Securities and Exchange Commission filed on behalf of Aristar Capital Management, LLC of which Mr. Smith disclaims beneficial ownership of 697,303 shares (post-split 69,730 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.



(3)

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.

(4)

Information obtained from a Schedule 13G/A filed with the SEC on January 9, 2018. Pursuant to this Schedule 13G/A: (i) Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Master Fund, Ltd. beneficially own 2,615,123 shares (post-split 261,512 shares) and 0 shares of our Common Stock, respectively, and (ii) Sabby Management, LLC and Hal Mintz each beneficially own 2,615,123 shares (post-split 261,512 shares) of our Common Stock. Sabby Management, LLC and Hal Mintz do not directly own any shares of Common Stock, but each indirectly owns 2,615,123 shares (post-split 261,512 shares) shares of our Common Stock. Sabby Management, LLC, a Delaware limited liability company, indirectly owns 2,615,123 shares (post-split 261,512 shares) of Common Stock because it serves as the investment manager of Sabby Healthcare Master Fund, Ltd. and Sabby Volatility Warrant Master Fund, Ltd., Cayman Islands companies. Mr. Mintz indirectly owns 2,615,123 shares (post-split 261,512 shares) of our Common Stock in his capacity as manager of Sabby Management, LLC. The principal business address of Sabby Healthcare Master Fund, Ltd. and 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 principal business address of Sabby Management, LLC and Hal Mintz is 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 Company had a related party receivable balance of \$0 and \$103,017 as of December 31, 2017 and 2016, respectively. This related party receivable in 2016 reflects a percent of labor that our former Chief Scientific Officer, Dr. Schreiber performed at the time Pelican was our former subsidiary.



The following is a summary of transactions since January 1, 2016 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 2017 Director Compensation and Part III, Item 11. Executive Compensation:

On March 8, 2017, we entered into a Stock Purchase Agreement with Pelican, and the majority of the stockholders of Pelican to purchase outstanding capital stock of Pelican. On April 28, 2017, we completed the acquisition of 80% of Pelican's common stock. 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. Pelican has been awarded a \$15.2 million grant to fund preclinical and some clinical activities from CPRIT. Jeff Wolf, through one or more of his affiliated entities, and Edward B. Smith, III and entities controlled by Mr. Smith sold approximately 84.7% of their shares of the capital stock of Pelican. Mr. Wolf was the managing member of a limited liability company (the LLC) that at the time of the Pelican Acquisition owned 60.1% of the outstanding capital stock of Pelican and Mr. Wolf directly and through entities owned by him owned 31.6% of the membership interests of the LLC. Mr. Smith directly and through entities that he controlled held approximately 10.2% of Pelican's outstanding capital stock at the time of the Pelican Acquisition and Mr. Smith directly and indirectly through an entity he controlled at the time of the Pelican Acquisition owned an aggregate of 23.1% of the membership interests of the LLC. Taylor Schreiber, M.D., Ph.D. our former Chief Scientific Officer, held less than 1% of Pelican's total outstanding capital stock at the time of the Pelican Acquisition and indirectly through an entity he controlled, at the time of the Pelican Acquisition owned 5% of the limited liability company at the time of the Pelican Acquisition. Dr. Schreiber also sold approximately 84.7% of his shares of the capital stock of Pelican in order to meet the 80% closing condition, on the same terms as the other participating Pelican stockholders. John Monahan, Ph.D. owned 0.46% of the LLC. In addition, a trust for which Mr. Wolf does not serve as the trustee for the benefit of Mr. Wolf's children directly owned 2.2% of Pelican's total outstanding capital stock and at the time of the Pelican Acquisition owned 10% of the membership interests of the LLC. Mr. Wolf disclaims beneficial ownership of all shares held by the trust.

Equity awards granted to our executive officers and directors during 2017 and on January 8, 2018 are disclosed under the sections of this Annual Report on Form 10-K entitled Part III, Item 10. Directors, Executive Officers and Corporate Governance 2017 Director Compensation and Part III, Item 11. Executive Compensation.

## 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, 2017 and 2016 by BDO USA, LLP.

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Audit Fees and Expenses (1)	\$ 289,000	\$ 169,500

(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, 2017 and 2016.

1. Report of Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2017 and 2016
3. Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2017 and 2016
4. Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017 and 2016
5. Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016
6. Notes to Consolidated Financial Statements

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

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

**Exhibit**

<b>No.</b>	<b>Description</b>
1.1	<u>At Market Issuance Sales Agreement</u> , by and between Heat Biologics, Inc. and FBR Capital Markets & Co. dated August 15, 2016 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
1.2	<u>Underwriting Agreement</u> , dated November 17, 2017, between Heat Biologics, Inc. and Aegis Capital Corp. (previously filed as Exhibit 1.1 to Heat Biologics, Inc.'s Current Report on Form 8-K (File No. 001-35994) filed with the Securities and Exchange Commission on November 17, 2017)
1.3	<u>Common Stock Sales Agreement</u> , 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))

- 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 Amended and Restated Bylaws, 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))
- 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 July 17, 2017 (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 on January 19, 2018 (File No. 001-35994))
- 4.1 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.2 First Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.3 Second Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.4 Third Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.5 Fourth Amendment of the 2009 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))

- 4.6 Warrant issued to Square 1 Bank (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.7 Warrant issued to North Carolina Biotechnology Center (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
- 4.8 Specimen Common Stock Certificate of Heat Biologics, Inc. (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.9 Form of Stock Purchase Agreement by and among Heat Biologics, Inc. and the Series B investors (Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted portions have been filed with the Commission) ## (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 4.10 Form of Representative's Warrant (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
- 4.11 Amendment to Stock Warrant with North Carolina Biotechnology Center (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
- 4.12 2014 Stock Incentive Plan## (previously filed as an exhibit to the Registration Statement on Form S-8 with the Securities and Exchange Commission on June 13, 2014 (File No. 333-196763))
- 4.13 Warrant issued to Square 1 Bank (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 25, 2014 (File No. 001-35994))
- 4.14 First Amendment to Loan and Security Agreement (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on June 24, 2015 (File No. 001-35994))
- 4.15 Form of Warrant (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 3, 2016 (File No. 001-35994))
- 4.16 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))
- 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 Loan and Security Agreement with Square 1 Bank dated August 7, 2012 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.14 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))
- 10.15 First Amendment to Loan and Security Agreement with Square 1 Bank dated November 30, 2012 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.16 Second Amendment to License Agreement (UMSS-114) dated August 11, 2009 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.17 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))
- 10.18 Second Amendment to Loan and Security Agreement with Square 1 Bank dated January 14, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.19 Third Amendment to Loan and Security Agreement with Square 1 Bank dated February 28, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.20 Fourth Amendment to Loan and Security Agreement with Square 1 Bank dated March 19, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.21 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))
- 10.22 Fifth Amendment to the Loan and Security Agreement with Square 1 Bank dated April 18, 2013 (previously filed as an exhibit to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
- 10.23 Employment Agreement, dated as of October 1, 2013, by and between Melissa Price and the Company## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on October 1, 2013 (File No. 001-35994))
- 10.24 Employment Agreement, dated as of December 16, 2013, by and between Anil K. Goyal and the Company## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on December 19, 2013 (File No. 001-35994))
- 10.25 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))
- 10.26



- Amendment to Employment Agreement, dated as of January 20, 2014 between the Company and Melissa Price## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994))
- 10.27 Employment Agreement, dated as of March 3, 2014 between the Company and Taylor Schreiber ## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 5, 2014 (File No. 001-35994))
- 10.28 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))
- 10.29 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))
- 10.30 Loan and Security Agreement dated August 22, 2014 by and between Square 1 Bank, the Company and Heat Biologics I, Inc., Heat Biologics III, Inc. and Heat Biologics IV, Inc. (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on August 25, 2014 (File No. 001-35994))
- 10.31 Amendment to Employment Agreement dated January 12, 2015 between the Company and Melissa Price## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994))

- 10.32 Amendment to Employment Agreement dated January 12, 2015 between the Company and Anil Goyal## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994))
- 10.33 Amendment to Employment Agreement dated January 12, 2015 between the Company and Taylor Schreiber## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 16, 2015 (File No. 001-35994))
- 10.34 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))
- 10.35 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))
- 10.36 Amendment to Employment Agreement between the Company and Taylor Schreiber, M.D., Ph.D., dated July 23, 2015## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
- 10.37 Amendment to Employment Agreement between the Company and Melissa Price, Ph.D., dated July 23, 2015## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
- 10.38 Amended and Restated Heat Biologics, Inc. 2014 Stock Incentive Plan## (previously filed as Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 22, 2015))
- 10.39 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))
- 10.40 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))
- 10.41 Employment Agreement, dated as of November 30, 2015 between the Company and Timothy Creech## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on December 1, 2015 (File No. 001-35994))
- 10.42 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))
- 10.43 Amendment to Employment Agreement between the Company and Melissa Price, dated January 11, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))
- 10.44 Amendment to Employment Agreement between the Company and Taylor Schreiber, dated January 11, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))
- 10.45 Amendment to Employment Agreement between the Company and Anil Goyal dated January 11, 2016 ##(previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))
- 10.46 Amendment to Employment Agreement between the Company and Timothy Creech dated January 11, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))

- 10.47 Second Amendment to Loan and Security Agreement between the Company and Pacific Western Bank and Heat Biologics, Inc., Heat Biologics I, Inc., Heat Biologics III, Inc., and Heat Biologics IV, Inc. dated February 29, 2016 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on March 3, 2016 (File No. 001-35994))
- 10.48 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))
- 10.49 Amendment to Employment Agreement between the Company and Melissa Price, dated April 1, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
- 10.50 Amendment to Employment Agreement between the Company and Taylor Schreiber, dated April 1, 2016## (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
- 10.51 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))

- 10.52 Severance Agreement between the Company and Timothy Creech, dated April 5, 2016 Previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
- 10.53 Severance Agreement between the Company and Anil Goyal, dated April 5, 2016 (previously filed as an exhibit to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994)
- 10.54 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))
- 10.55 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))
- 10.56 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))
- 10.57 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)
- 10.58 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))
- 10.59 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))
- 10.60 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))
- 10.61 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))
- 10.62 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))
- 10.63 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))
- 10.64 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)
- 10.65 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))
- 10.66 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))
- 10.67 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))
- 10.68 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))

- 10.69 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))
- 10.70 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))
- 10.71 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))
- 10.72 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))
- 10.73 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))
- 10.74 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))
- 10.75 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))
- 10.76 Amendment to Employment Agreement with Ann Rosar 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))
- 10.77 Form of Incentive Stock Option Agreement under the 2017 Stock Incentive Plan##\*
- 10.78 Form of Non-Statutory Stock Option Agreement under the 2017 Stock Incentive Plan##\*
- 10.79 Form of Restricted Stock Unit Award Agreement under the 2017 Stock Incentive Plan##\*
- 21.1 List of Subsidiaries \*
- 23.1 Consent of Independent Registered Public Accounting Firm (BDO USA, LLP)\*
- 31.1 Certification of Jeffrey Wolf, Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) \*
- 31.2 Certification of Ann Rosar, Principal Financial 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 Ann Rosar, 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.

**Item 16.**

***Form 10-K Summary***

Not applicable.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 2<sup>nd</sup> day of March, 2018.

**HEAT BIOLOGICS, INC.**

By: /s/ Jeffrey Wolf  
Jeffrey Wolf  
Chief Executive Officer and Chairman of the Board  
(Principal Executive Officer)  
Date: March 2, 2018

By: /s/ Ann A. Rosar  
Ann A. Rosar  
Vice President of Finance  
(Principal Financial and Principal Accounting Officer)  
Date: March 2, 2018

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Jeffrey Wolf Jeffrey Wolf	Chief Executive Officer, President and Chairman of the Board  (Principal Executive Officer)	March 2, 2018
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 2, 2018
/s/ John K.A. Prendergast, Ph.D. John K.A. Prendergast, Ph.D.	Director	March 2, 2018
/s/ Edward B. Smith Edward B. Smith	Director	March 2, 2018





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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) and subsidiaries as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, 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 and subsidiaries at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern

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 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 2, 2018

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**HEAT BIOLOGICS, INC.****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Current Assets</b>		
Cash and cash equivalents	\$ 9,763,067	\$ 7,842,667
Accounts receivable	14,833	82,305
Prepaid expenses and other current assets	1,967,257	338,049
<b>Total Current Assets</b>	<b>11,745,157</b>	<b>8,263,021</b>
<b>Property and Equipment, net</b>	<b>286,891</b>	<b>359,592</b>
<b>Other Assets</b>		
Restricted cash	2,292	101,171
In-process R&D	5,866,000	
Goodwill	2,189,338	
Deposits	69,798	69,798
Related party receivable		103,017
Deferred financing costs	30,000	
<b>Total Other Assets</b>	<b>8,157,428</b>	<b>273,986</b>
<b>Total Assets</b>	<b>\$ 20,189,476</b>	<b>\$ 8,896,599</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,033,680	\$ 290,058
Deferred revenue	7,026,388	
Accrued expenses and other liabilities	2,276,431	1,305,173
<b>Total Current Liabilities</b>	<b>10,336,499</b>	<b>1,595,231</b>
<b>Long Term Liabilities</b>		
Other long-term liabilities	160,559	461,434
Deferred tax liability	1,302,220	
Contingent consideration	2,609,289	
<b>Total Liabilities</b>	<b>14,408,567</b>	<b>2,056,665</b>
Commitments and Contingencies		

**Stockholders' Equity**

Common stock, \$.0002 par value; 100,000,000 shares authorized,  
4,200,310 and 2,620,439 issued and outstanding at December 31,  
2017 and 2016, respectively

	840	524
Additional paid-in capital	76,382,262	65,872,943
Accumulated deficit	(68,846,326)	(57,004,655)
Accumulated other comprehensive loss	(166,025)	(72,231)
<b>Total Stockholders' Equity - Heat Biologics, Inc</b>	<b>7,370,751</b>	<b>8,796,581</b>
<b>Non-Controlling Interest</b>	<b>(1,589,842)</b>	<b>(1,956,647)</b>
<b>Total Stockholders' Equity</b>	<b>5,780,909</b>	<b>6,839,934</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 20,189,476</b>	<b>\$ 8,896,599</b>

All share numbers have been adjusted for the one-for ten reverse stock split effective January 19, 2018

See Notes to Consolidated Financial Statements

**HEAT BIOLOGICS INC.****Consolidated Statements of Operations and Comprehensive Loss**

	<b>Year ended, December 31,</b>	
	<b>2017</b>	<b>2016</b>
Revenue:		
Grant and licensing revenue	\$ 1,519,943	\$ 341,643
Operating expenses:		
Research and development	8,267,549	9,330,677
General and administrative	6,370,954	4,138,285
Change in fair value of contingent consideration	224,289	
Total operating expenses	14,862,792	13,468,962
Loss from operations	(13,342,849)	(13,127,319)
Interest income	22,167	31,142
Other income, net	101,276	670,781
Interest expense		(549,403)
Total non-operating income (expenses), net	123,443	152,520
Net loss before income tax benefit	(13,219,406)	(12,974,799)
Income tax benefit	809,540	
Net loss	(12,409,866)	(12,974,799)
Net loss - non-controlling interest	(568,195)	(400,847)
Net loss attributable to Heat Biologics, Inc.	\$ (11,841,671)	\$ (12,573,952)
Net loss per share attributable to Heat Biologics, Inc.- basic and diluted	\$ (3.08)	\$ (7.15)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	3,845,342	1,758,621
Other comprehensive loss:		
Net loss	(12,409,866)	(12,974,799)
Unrealized (loss) gain on foreign currency translation	(93,794)	14,353
Total comprehensive loss	(12,503,660)	(12,960,446)
Comprehensive loss - non-controlling interest	(568,195)	(400,847)
Comprehensive loss attributable to Heat Biologics, Inc.	\$ (11,935,465)	\$ (12,559,599)

All share numbers have been adjusted for the one-for ten reverse stock split effective January 19, 2018

See Notes to Consolidated Financial Statements

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## 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, 2015	\$ 169	\$ 48,567,648	\$ (44,430,703)	\$ (86,584)	\$ (1,555,800)	\$ 2,494,730
Public offering, 910,000 shares, net of underwriters discounts	182	6,287,068				6,287,250
Exercise of warrants, 386,343 shares	77	3,863,352				3,863,429
Issuance of common stock, 479,138 shares	96	7,082,430				7,082,526
Stock issuance costs		(510,185)				(510,185)
Stock-based compensation		582,630				582,630
Other comprehensive gain (loss)				14,353		14,353
Net loss			(12,573,952)		(400,847)	(12,974,799)
Balance at December 31, 2016	524	65,872,943	(57,004,655)	(72,231)	(1,956,647)	6,839,934
Public offering, 575,000 shares, net of underwriters discounts	115	4,182,885				4,183,000
Public offering, 620,650 shares, net of underwriters discounts	124	2,446,855				2,446,979
Issuance of common stock,	47	2,463,133				2,463,180

234,858 shares Issuance of common stock for acquisition of Pelican, 133,106 shares	27	1,051,973				1,052,000
Acquisition of non-controlling interest of Pelican				935,000		935,000
Stock issuance costs		(324,654)				(324,654)
Stock-based compensation	3	689,127				689,130
Other comprehensive loss			(93,794)			(93,794)
Net loss			(11,841,671)		(568,195)	(12,409,866)
Balance at December 31, 2017	\$ 840	\$ 76,382,262	\$ (68,846,326)	\$ (166,025)	\$ (1,589,842)	\$ 5,780,909

All share numbers have been adjusted for the one-for ten reverse stock split effective January 19, 2018

See Notes to Consolidated Financial Statements

**HEAT BIOLOGICS, INC.****Consolidated Statements of Cash Flows**

	<b>For the year ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (12,409,866)	\$ (12,974,799)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	134,084	132,077
Amortization of deferred financing costs and debt issuance costs		218,827
Amortization of held to maturity investment premium		32,733
Stock based compensation	689,130	582,630
Change in fair value of contingent consideration	224,289	
Increase (decrease) in cash arising from changes in assets and liabilities:		
Accounts receivable	67,767	(82,440)
Prepaid expenses and other current assets	(1,525,306)	532,872
Related party receivable		(45,000)
Deferred financing costs	(30,000)	
Accounts payable	(175,901)	(1,690,048)
Deferred revenue	7,026,388	
Deferred tax liability	(809,540)	
Accrued expenses and other liabilities	806,158	(542,255)
Other long-term liabilities	(300,875)	311,686
<b>Net Cash Used in Operating Activities</b>	<b>(6,303,672)</b>	<b>(13,523,717)</b>
<b>Cash Flows from Investing Activities</b>		
Proceeds from maturities of short-term investments		6,656,910
Purchase of Pelican, net	(468,801)	
Purchase of property and equipment	(61,383)	(45,936)
<b>Net Cash Used in Investing Activities</b>	<b>(530,184)</b>	<b>6,610,974</b>
<b>Cash Flows from Financing Activities</b>		
Proceeds from public offerings, net of underwriting discounts	6,629,979	6,287,250
Proceeds from the issuance of common stock, net of commissions	2,463,180	7,082,526
Proceeds from the exercise of warrants		3,863,429
Stock issuance costs	(324,654)	(488,585)
Payments on long term debt		(6,941,821)
<b>Net Cash Provided by Financing Activities</b>	<b>8,768,505</b>	<b>9,802,799</b>
	(14,249)	12,656

**Effect of exchange rate changes on cash and cash equivalents**

<b>Net Increase in Cash and Cash Equivalents</b>		1,920,400		2,902,712
<b>Cash and Cash Equivalents - Beginning of Period</b>		7,842,667		4,939,955
<b>Cash and Cash Equivalents - End of Period</b>	\$	9,763,067	\$	7,842,667
<b>Supplemental Disclosure for Cash Flow Information</b>				
Contingent consideration	\$	2,385,000	\$	
Issuance of common stock for purchase of Pelican	\$	1,052,000	\$	
Interest paid	\$		\$	330,576

All share numbers have been adjusted for the one-for ten reverse stock split effective January 19, 2018

See Notes to Consolidated Financial Statements

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**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1.**

***Organization***

Heat Biologics, Inc. ( Heat or the Company ) is a biopharmaceutical company developing approaches to activate and co-stimulate a patient's immune system against cancer. Our co-stimulatory antibody is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram the immunity and provide a long-term, durable clinical effect. Our T-cell Activation Platform (TCAP) produces therapies designed to turn cold tumors hot, and be administered in combination with checkpoint inhibitors and other immuno-modulators to increase effectiveness. Unlike many other patient specific immunotherapy approaches, our drugs are off-the-shelf which means that we can administer drug immediately without extracting patient material at a substantially lower cost. Our TCAP product candidates from our *ImPACT*<sup>®</sup> and *ComPACT* platforms are produced from allogeneic cell lines expressing tumor-specific proteins common among cancers. We are currently enrolling patients in our Phase 2 clinical trial for non-small cell lung cancer (NSCLC), in combination with Bristol-Myers Squibb's nivolumab (Opdiv<sup>®</sup>). We also have numerous pre-clinical programs at various stages of development.

Heat owns 92.5% interest in its subsidiary, Heat Biologics I, Inc. On May 30, 2012, Heat formed two-wholly owned subsidiaries, Heat Biologics III, Inc. ( Heat III ) and Heat Biologics, IV, Inc. ( Heat IV ). Heat formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012. Heat also formed Heat Biologics Australia Pty LTD, a wholly-owned proprietary company, registered in Australia on March 14, 2014. On October 25, 2016, Heat formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, and dengue and yellow fever. On April 28, 2017, the Company completed the acquisition of an 80% controlling interest in Pelican Therapeutics, Inc. ( Pelican ), a related party prior to acquisition. Operations of Pelican are included in the consolidated statement of operations and comprehensive loss from the acquisition date.

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

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*

*Going Concern*

The accompanying consolidated financial statements have been prepared on a going concern basis. The Company has an accumulated deficit of approximately \$68.8 million as of December 31, 2017 and a net loss of approximately \$12.4 million for the year ended December 31, 2017, and has not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the audited financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. To meet its capital needs, the Company is considering multiple alternatives, including, but not limited to, additional equity financings (including through the at-the-market Issuance Sales Agreement that it entered into with H.C. Wainwright & Co., LLC ( H.C. Wainwright ) in January 2018, partnerships, collaborations, debt financings, and other funding transactions. There can be no assurance that the Company will be able to meet the requirements for use of the H.C. Wainwright Sales Agreement or to complete any such transactions on acceptable terms or otherwise. The Company has, and plans to continue to direct its resources primarily to advance the Phase 2 trial evaluating HS-110 in combination with nivolumab, a Bristol-Myers Squibb PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC). Further goals for both Heat and Pelican in 2018 are focused on expanding their clinical and regulatory pipeline and milestones; building research areas and broadening therapeutic applications for its compounds; and securing partnerships and/or collaborations.

If the Company is unable to obtain the necessary capital required to maintain operations, it will need to pursue a plan to license or sell its assets, seek to be acquired by another entity and/or cease operations.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

***Principles of Consolidation***

The consolidated financial statements include the accounts of Heat Biologics, Inc. and its subsidiaries, Heat Biologics I, Inc. ( Heat I ), Heat Biologics III, Inc. ( Heat III ), Heat Biologics IV, Inc. ( Heat IV ), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd, and Zolovax, Inc. Additionally, beginning April 28, 2017 the accompanying consolidated financials include Pelican. 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, 2017 and 2016, Heat held a 92.5% controlling interest in Heat I. The December 31, 2017 year-end financials include the 80% controlling interest in Pelican as of April 28, 2017. 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.

***Use of Estimates***

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

***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. The Company had a restricted cash balance of \$2,292 and \$101,171 at December 31, 2017 and 2016, respectively. The United States Patent and Trade Office ( USPTO ) requires the Company to maintain an account with a minimum of \$1,000 to be used to pay fees associated with new trademarks of the Company and one of the Company's lenders required a minimum \$100,000 cash balance to be maintained with the lending bank to secure the Company credit card during 2016.

### ***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, 2017 and 2016, cash amounts in excess of \$250,000 were not fully insured. The uninsured cash balance as of December 31, 2017 was \$9,513,067. 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 and computer equipment, and seven years for furniture and fixtures.

### ***Net Loss per Share***

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



**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

***Fair Value of Financial Instruments***

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, restricted cash, related party 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 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.

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, 2017:

	<b>Contingent Consideration</b>	
Balance at December 31, 2016	\$	
Acquisition of Pelican		2,385,000
Change in fair value		224,289
Balance at December 31, 2017	\$	2,609,289

The change in the fair value of the contingent consideration of \$224,289 for the year ended December 31, 2017 was primarily due to the effect of the change in discount rate 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.

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, 2017:

	<b>Valuation Methodology</b>	<b>Significant Unobservable Input</b>	<b>Weighted Average (range, if applicable)</b>
Contingent Consideration	Probability weighted income approach	Milestone dates	2019-2025
		Discount rate	11.79% to 3.91%
		Probability of occurrence	34.2% to 80%

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

***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, 2017 and 2016, 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, 2017 and 2016, 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. 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 may be adjusted during 2018 when additional information is obtained. Additional information that may affect our provisional amounts would include further clarification and guidance on how the Internal Revenue Service will implement the Tax Act, including guidance with respect to guidance on how state taxing authorities will implement tax reform and the related effect on our state income tax returns, completion of its 2017 tax return filings, and the potential for additional guidance from the Financial Accounting Standards Board related to the Tax Act.

***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, 2017 and 2016 represents the average time that options are expected to be outstanding based on the average of the vesting term and the contractual term of the option. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards. The measurement of nonemployee share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense in the period over which services are received.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

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

Net loss attributable to non-controlling interests is the result of the Company's consolidation of subsidiaries of which it does not own 100%. The Company's net loss attributable to non-controlling interests relates to the University of Miami's ownership in Heat I, for the years ended December 31, 2017 and 2016, and the remaining 20% ownership of Pelican that Heat does not own as of December 31, 2017.

***Revenue Recognition***

Revenue generally consists of research funding from the Company's CPRIT Grant and a research funding agreement with Shattuck that terminated on January 31, 2017. 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.

***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 3).

***Goodwill and In-Process Research and Development***

We classify 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. We determine the useful lives of definite-lived intangible assets after considering specific facts and circumstances related to each intangible asset. Factors we consider 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 on the anniversary of the acquisition which will occur April 1, 2018, 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 will qualitatively test the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate evidence a potential impairment exists, using a fair value based test. No impairment existed at December 31, 2017.

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 we acquire, 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 we become 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, we 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 (see Note 5).

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

***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 are presented in long-term liabilities in the consolidated balance sheets (see Note 3).

***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 May 2017, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting (ASU 2017-09)*. This ASU provides that an entity should account for the effects of a modification unless the fair value, the vesting conditions of the modified award and the classification of the modified award (equity or liability instrument) are the same as the original award immediately before the modification. The provisions of this ASU are effective for years beginning after December 15, 2017, with early adoption permitted. The Company's early adoption of this standard in the third quarter of 2017 did not have a significant impact to the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment (Topic 350)*. This standard eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. This guidance is effective for interim and annual goodwill impairment tests in fiscal years beginning after December 15, 2019 with early adoption permitted. This guidance must be applied on a prospective basis. The Company chose to adopt this standard beginning in the third quarter of 2017 and the early adoption of this standard did not have a significant impact to the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805)* to clarify the definition of a business, which is fundamental in the determination of whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses combinations. The updated guidance requires that in order to be considered a business the integrated set of assets and activities acquired must include, at a minimum, an input and process that contribute to the ability to create output. If substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar assets, it is not considered a business, and therefore would not be considered a business combination. The update is effective for fiscal years beginning after December 15, 2018, and interim periods with fiscal years beginning after December 15, 2019, with early adoption permitted. The Company has not determined the impact of this standard and does not plan early adoption of this standard.



**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09)*. Under ASU 2016-09, the tax effects of stock compensation will be recognized as income tax expense or benefit to the Company's income statement and the tax effects of exercised or vested awards will be treated as discrete items in the reporting period in which they occur. Along with other income tax cash flows, excess tax benefits will be classified as operating activities, and cash paid by the Company when directly withholding shares for tax withholding purposes will be classified as financing activities. The Company has elected to continue to account for forfeitures when they occur. The adoption of ASU 2016-09 did not have a material impact to the Company's consolidated financial statements.

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (ASU 2014-09)*, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In July 2015, the FASB voted to defer the effective date of the new standard until fiscal years beginning after December 15, 2017 with early application permitted for fiscal years beginning after December 15, 2016. The Company has substantially completed its initial review of the CPRIT contract and the related guidance. The CPRIT contract includes reimbursement for qualified expenditures incurred. Grant revenue is recognized as work is performed and qualifying costs are incurred. The Company, based on its initial analysis, does not anticipate a material effect on the timing and measurement of revenue. The Company anticipates using the modified retrospective method of adoption and is currently evaluating the required disclosures.

3.

***Acquisition of Pelican Therapeutics***

On April 28, 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. Operations of Pelican are included in the consolidated statements of operations and comprehensive loss from the acquisition date. 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, the Company paid to the Pelican Stockholders that executed the Stock Purchase Agreement (the Participating Pelican Stockholders ) an aggregate of \$0.5 million (the Cash Consideration ), and issued to the Participating Pelican Stockholders 133,106 shares of the Company's 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 Cash Consideration will be reduced by the amount by which certain of Pelican's accrued liabilities are not satisfied for less than \$0.25 million. The Cash Consideration and Stock Consideration are currently being distributed but have not been finalized as of December 31, 2017.

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.

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

The fair value of these future milestone payments is reflected in the contingent consideration account 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 7.68% based on the median yield of publicly traded non-investment grade debt of companies in the pharmaceutical industry. The Company performs an analysis on a quarterly basis and as of December 31, 2017, the Company determined the change in the estimated fair value of the contingent consideration was approximately \$0.2 million for the year ended December 31, 2017.

We have recorded the assets purchased and liabilities assumed at their estimated fair value in accordance with FASB ASC Topic 805: Business Combinations. The purchase price exceeded the fair value of the net assets acquired resulting in goodwill of approximately \$2.2 million. The identifiable indefinite-lived intangible assets consists of in-process R&D of approximately \$5.9 million. The estimated fair value of the IPR&D was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company utilized corporate bond yield data observed in the bond market to develop the discount rate utilized in the cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions. Operations of the acquired entity are included in the consolidated statements of operations from the acquisition date. Fees and expenses associated with the acquisition were approximately \$0.6 million for the twelve months ended December 31, 2017 and are reported in our general and administrative expense.

The purchase price has been allocated to the assets and liabilities as follows:

**Aggregate consideration:**

Cash consideration	\$	500,000
Stock consideration	\$	1,052,000
Contingent consideration	\$	2,385,000
<b>Total Consideration</b>	<b>\$</b>	<b>3,937,000</b>

**Purchase price allocation:**

Cash acquired	\$	31,199
In-process R&D	\$	5,866,000
Goodwill	\$	2,189,338
Deferred tax liability	\$	(2,111,760)
Net liabilities assumed	\$	(1,102,777)
Fair value of non-controlling interest	\$	(935,000)
<b>Total purchase price</b>	<b>\$</b>	<b>3,937,000</b>

The purchase price allocation presented herein is preliminary. The final purchase price allocation will be determined after completion of an analysis to determine the fair value of all assets acquired and liabilities assumed, but in no event later than one year following completion of the Pelican acquisition. Any increase or decrease in the in-process R&D asset, as compared to the information shown herein, could also change the portion of purchase price allocated to goodwill, and could impact the operating results of the Company following the acquisition due to differences in purchase price allocation and amortization related to some of these assets and liabilities.

Goodwill is 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 arises largely from 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.

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

In May 2016, Pelican was awarded a \$15.2 million CPRIT Grant from CPRIT for development of Pelican's lead product candidate, PTX-25. The CPRIT Grant is expected to allow Pelican to develop PTX-25 through a 70-patient Phase 1 clinical trial. The Phase 1 clinical trial will be designed to evaluate PTX-25 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 three year project.

As of December 31, 2017, we have provided approximately \$1.2 million in matching funding and we have \$6.4 million remaining to provide over the three-year project, with \$2.9 million remaining for the second CPRIT fiscal year (June 2017 through May 2018) of the award, and \$3.5 million for the third CPRIT fiscal year (June 2018 through May 2019).

As of December 31, 2017, CPRIT has provided \$8.3 million of the total \$15.2 million grant. The remaining \$6.9 million will become available in the third CPRIT fiscal year (June 2018 through May 2019).

Since its acquisition on April 28, 2017, Pelican has contributed net revenue and net loss of approximately \$1.5 million and \$1.7 million, respectively, which are included in the Company's consolidated statement of operations for the year ended December 31, 2017, and exclude acquisition and integration related expenses which are included in non-recurring and acquisition-related costs.

The following unaudited pro forma information presents the combined results of operations for the years ended December 31, 2017 and 2016, as if we had completed the Pelican acquisition at the beginning of fiscal 2016. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period.

<i>(in thousands except per share value)</i>	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Grant and licensing revenue	\$ 1,520	\$ 342
Net loss	(12,800)	(13,679)
Net loss: Non-controlling interest	(646)	(542)

Net loss attributable to Heat Biologics, Inc.	\$	(12,154)	\$	(13,137)
Net loss per share attributable to Heat Biologics, Inc. basic and diluted	\$	(3.16)	\$	(7.23)

## 4.

*Prepaid Expenses and Other Current Assets*

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

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Prepaid manufacturing expense	\$ 1,551,597	\$ 57,131
Prepaid insurance	218,750	217,500
Other prepaid expenses	87,937	63,418
Other current assets	108,973	
	\$ 1,967,257	\$ 338,049

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

5.

***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:

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Lab equipment	\$ 645,433	\$ 587,366
Computers	41,333	38,903
Furniture and fixtures	55,883	55,883
Total	742,649	682,152
Accumulated depreciation	(455,758)	(322,560)
Property and equipment, net	\$ 286,891	\$ 359,592

Depreciation expense totaled \$134,084 and \$132,077 for the years ended December 31, 2017 and 2016, respectively.

6.

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

The following table provides a rollforward of the Company's goodwill as of December 31, 2017:

**Goodwill**

Balance at December 31, 2016	\$	
Goodwill from acquisition of Pelican		2,189,338
Balance at December 31, 2017	\$	2,189,338

The following table provides a rollforward of the Company's in-process R&D as of December 31, 2017:

	<b>In-process R&amp;D</b>	
Balance at December 31, 2016	\$	
In-process R&D from acquisition of Pelican		5,866,000
Balance at December 31, 2017	\$	5,866,000

7.

***Accrued Expenses***

Accrued expenses consist of the following at:

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Accrued clinical trial expenses	\$ 1,504,240	\$ 580,218
Compensation and related benefits	542,434	642,532
Patent fees	40,000	40,000
Deferred rent	27,457	42,423
Other expenses	162,300	—
	\$ 2,276,431	\$ 1,305,173



**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

8.

***License Agreements***

*University of Miami*

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

The Company agreed to make minimum royalty payments of \$10,000 for three years beginning in 2010 that are due on the anniversary date of the agreement for License Agreement 97-14. Beginning in 2013, and thereafter for the life of the agreement, the minimum royalty payment shall be \$20,000 due on the same date. In July 2016, the Company and the University entered into an amendment 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 the University entered into a second amendment (“Amendment 2”) to License Agreement 97-14 to extend the foregoing payment due dates for all past due license fees and patent costs.

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

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

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

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

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

*University of Miami - Pelican*

The University of Miami owns 2.5% of Pelican's issued and outstanding common stock. For each agreement, the Company agreed to make minimum royalty payments of \$10,000 for three years beginning 2010 due on the anniversary date of the agreements. Beginning in 2013, and thereafter for the life of the agreements, the minimum royalty payments shall be \$20,000 due on the same date.

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**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

License 03–31, 05–39

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 the University entered into a second amendment (“Amendment 2”) to License Agreement 03–31, 05–39 to extend the foregoing payment due dates for all past due license fees and patent costs.

In February 2010, Pelican and the University entered into a third amendment (“Amendment 3”) to License Agreement 03–31, 05–39 to grant back to the University a certain non–exclusive license. In all other respects, the original agreement remained the same.

In October 2010, Pelican and the University entered into a fourth amendment (“Amendment 4”) to License Agreement 03–31, 05–39 to grant to the licensor a non–exclusive license right for certain technology as research reagents and research tools.

License I–176

On December 12, 2010, Pelican entered into another license agreement ( I–176 ) with the University for one component of complimentary technology to the July 11, 2008 agreement. Pelican agreed to pay the University 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 the University entered into a second amendment (“I-176 Amendment 2”) to License Agreement I-176 to extend the foregoing payment due dates for all past due license fees and patent costs.

#### UMM-143

On November 19, 2013, Pelican entered into another license agreement ( UMM-143 ) with the University for an exclusive license of complimentary technology and patent rights. Pelican agreed to pay the University a license issue fee of \$35,000, and agreed to make minimum royalty payments if the I-176 license agreement is terminated. No minimum royalty payments or milestone payments are due for any year in which the I-176 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, Heat entered into a non-exclusive evaluation and biological material license agreement with a not-for-profit corporation for evaluation and production of vaccines. In consideration for the evaluation and commercial use license, Heat agreed to pay the not-for-profit corporation a fee of \$5,000 and \$50,000, respectively. Heat has the option to renew the license once the original term has expired. Milestone payments are due upon certain events agreed upon by Heat and the not-for-profit corporation. In December 2015, Heat amended the evaluation and biological material license agreement to add additional cell lines in exchange for a one-time payment of \$1,000.

On August 30, 2010, Heat entered into an option agreement with the University of Michigan (“University II”) to acquire the right to negotiate an exclusive license for certain materials which include cancer cells and all unmodified derivatives of these cells. An option fee of \$2,000 was paid on September 8, 2010 to grant a period of nine months for

this consideration. In July 2011, the Company exercised the option to acquire the license for \$10,000.

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

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 we will derive any revenue from Shattuck.

Future minimum royalty payments for licenses as of December 31, 2017 are as follows (in thousands):

<b>Year ended December 31,</b>	
2018	64
2019	74
2020	103
2021	228
2022	784
Total	\$ 1,253

9.

***Stockholders Equity******Authorized Capital***

Heat has authorized 10,000,000 shares of Preferred Stock (par value \$0.0001) as of December 31, 2017 and 2016. As of December 31, 2017 and 2016, 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, 2017. On January 19, 2018, Heat announced a reverse stock split of its shares of common stock at a ratio of 1-for-10. The reverse stock took effect as of 11 p.m. ET on January 19, 2018, to trade on a post-split basis at the market open on January 22, 2018. During the company's annual shareholder meeting held June 29, 2017, shareholders approved the company's reverse stock split, and granted the board of directors the authority to implement and determine the exact split ratio. When the reverse stock split became effective, every 10 shares of the company's issued and outstanding common stock were combined into one share of common stock. Effecting the reverse stock split reduced the number of issued and outstanding common stock from approximately 42 million shares to approximately 4.2 million. Therefore, of the 100,000,000 common stock shares authorized, 4,200,310 and 2,620,439 common stock shares were issued and outstanding as of December 31, 2017 and 2016, respectively.

### Preferred Stock

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

#### *Automatic Conversion*

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



**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

*Optional Conversion*

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

In the event the Company at any time or from time to time after the Initial Series B Issuance Date shall issue additional shares of common stock without consideration or for consideration per share less than the Series A Conversion Price, Series B-1 Conversion Price, or Series B-2 Conversion Price, in effect on the date of and immediately prior to such issue, then the Series A Conversion Price, the Series B-1 Conversion Price, Series B-2 Conversion Price, shall be reduced, to a price determined by multiplying the Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price in effect by a fraction, (A) the numerator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of shares of common stock which the aggregate consideration received by the Company for the total number of Additional Shares of Common Stock so issued would purchase at the Series A Conversion Price, the Series B-1 Conversion Price, or the Series B-2 Conversion Price, as in effect immediately prior to such issuance, and (B) the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issuance, on a fully-diluted basis, plus the number of such Additional Shares of common stock so issued. As a result of the IPO, all outstanding shares of preferred stock were automatically converted to common stock.

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

*Dividends*

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

#### *Liquidation*

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

#### *Voting Rights*

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

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

***Financings***

The Company had entered into an at-the-market Issuance Sales Agreement with FBR Capital Markets Co. pursuant to which it has sold shares of its common stock through FBR by any method permitted that is deemed an at the market offering as defined in Rule 415 under the Securities Act of 1933, as amended (the Securities Act), including sales made directly on or through the NASDAQ Capital Market, the existing trading market for the Company's common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Sales of shares of common stock have been made pursuant to the Company's shelf registration statement on Form S-3 filed with the U.S. Securities and Exchange Commission (SEC), the base prospectus, dated October 23, 2014, filed as part of such registration statement and the prospectus supplement, dated August 15, 2016. FBR was entitled to compensation at a fixed commission rate up to 3.0% of the gross proceeds per share sold through it as sales agent under the sales agreement. Beginning in August 2016 and through December 31, 2016, the Company sold 479,138 shares of common stock under the FBR Sales Agreement resulting in net proceeds of approximately \$6.8 million. For the year ended December 31, 2017, the Company sold an additional 234,858 shares of common stock under the Sales Agreement resulting in net proceeds of approximately \$2.3 million after FBR's commission and other expenses. On November 3, 2017, the Company terminated its At Market Issuance Sales Agreement with FBR.

On March 28, 2017, the Company sold pursuant to the terms of an Underwriting Agreement (the Underwriting Agreement) the Company sold pursuant to the terms of an Underwriting Agreement (the Underwriting Agreement (Aegis)), as representative of the several underwriters named therein (the Underwriters), 500,000 shares of the Company's common stock and 75,000 additional shares of the common stock to cover over-allotments at an offering price of \$8.00 per share, (the March Offering). The net proceeds to the Company from the March Offering were approximately \$4.1 million, after deducting underwriting discounts, commissions, and other third party offering expenses. The Underwriting Agreement contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the Securities Act), other obligations of the parties and termination provisions.

In November 2017, the Company sold pursuant to the terms of an Underwriting Agreement (the Underwriting Agreement) the Company sold pursuant to the terms of an Underwriting Agreement (the Underwriting Agreement (Aegis)), as representative of the several underwriters named therein (the Underwriters), 581,395 shares of the Company's common stock, and 39,255 additional shares of the common stock to cover over-allotments at an offering price of \$4.30 per share, (the Offering). The net proceeds to the Company from the Offering were approximately \$2.4 million, after deducting underwriting discounts, commissions, and other third party offering expenses. The Underwriting Agreement contains customary representations, warranties, and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under

the Securities Act of 1933, as amended (the Securities Act ), other obligations of the parties and termination provisions.

### ***Restricted Stock***

In January 2017, the Company granted 42,850 restricted stock units to the employees of the company in which 25%, (10,713 restricted stock units) vested immediately and the remainder will vest on each anniversary of the grant date over a three-year period contingent on continued employment with the Company. On December 30, 2016, the Company granted 7,500 restricted stock units to the Chief Executive Officer in which 25% (1,875 restricted stock units) vested immediately and the remainder will vest on each anniversary of the grant date over a three year period. Additionally, the Company issued 500 shares to one of its employees during the year ended December 31, 2016. The Company recognized \$169,517 and \$24,278 in stock-based compensation expense for employees related to restricted stock awards during the years ended December 31, 2017 and 2016, respectively.

The Company recognized stock-based compensation related to issuance of restricted stock to nonemployees in exchange for services totaling \$31,000 and \$27,996 for the years ended December 31, 2017 and 2016, respectively.

### ***Common Stock Warrants***

In connection with our 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 upon exercise. The warrants expire five years from the issuance date.

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

On March 10, 2011, the Company issued warrants to purchase 3,261 shares of common stock to non-employee placement agents in consideration for a private equity placement transaction. The warrants have an exercise price of \$4.80 per share and expire 10 years from the issuance date. In February 2014, 1,523 warrants were exercised in cashless transactions that resulted in the issuance of 1,432 shares of common stock and 1,738 are outstanding.

During the year ended December 31, 2017 there were no warrant exercises. During the year ended December 31, 2016, in connection with the March 23, 2016 public offering, the Company issued 910,000 shares of common stock and warrants to purchase 682,500 shares of common stock (after the effect of the stock split). Each share of common stock was sold together with a warrant to purchase 0.75 of a share of common stock. The warrants have an exercise price of \$10.00 per share and expire five years from the issuance date. These warrants do not meet the criteria required to be classified as liability awards and therefore the Company concluded that the warrants are considered equity instruments. The fair value of the common stock warrants as of the issuance date was approximately \$2,522,754. As of December 31, 2017, warrants from the March 2016 offering for 386,341 shares of common stock issuable at \$10.00 per share have been exercised and 296,159 are outstanding.

The Company has a total of 310,397 warrants outstanding at a weighted average exercise price of \$14.60 to purchase its common stock as of December 31, 2017. These warrants are summarized as follows:

<b>Issuance Date</b>	<b>Number of Shares</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
3/10/2011	1,738	\$ 4.80	3/10/2021
7/23/2013	12,500	\$125.00	7/23/2018
3/23/2016	296,159	\$ 10.00	3/23/2021

The following table summarizes the warrant activity of the Company's common stock warrants:

<b>Common Stock</b>	
	<b>Warrants</b>
Outstanding, December 31, 2015	14,238
March 23, 2016 public offering	682,500
Exercised	(386,341)
Expired	
Outstanding, December 31, 2016	310,397
Exercised	

Expired

Outstanding, December 31, 2017

310,397

*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. As of December 31, 2017 and 2016, there were 24,042 and 24,977 stock options outstanding under the 2009 Plan, respectively.

**HEAT BIOLOGICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)*****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, 2017 and 2016, there were 232,768 and 88,699 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, 2017 there were 10,000 stock options outstanding under the 2017 Plan. There were no options outstanding under the 2017 Plan as of December 31, 2016.

There are 553,196 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:

	<b>For the years ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Employee stock options	\$ 474,251	\$ 527,697
Non-employee stock options	14,362	2,664
Employee stock awards	169,517	24,276
Non-employee stock awards	31,000	27,993
	<b>\$ 689,130</b>	<b>\$ 582,630</b>

*Stock Options*

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

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Dividend yield	0.0%	0.0%
Expected volatility	76.35-79.08%	72.95-78.54%
Risk-free interest rate	1.86-2.26%	1.36-2.25%
Expected term (years)	5.8-7.8	5.4 - 6.3

The risk-free interest rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options. The Company used an average historical stock price volatility based on an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms, as the Company had limited to no trading history for its common stock. Expected term represents the period that the Company's stock option grants are expected to be outstanding. The Company elected to utilize the simplified method to estimate the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Expected dividend yield was considered to be 0% in the option pricing formula since the Company had not paid any dividends and had no plans to do so in the future. As required by ASC 718, the Company reviews recent forfeitures and stock compensation expense. Additionally, the Company conducts a sensitivity analysis. Based on these evaluations the Company currently does not apply a forfeiture rate.



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

The Company recognized \$488,613 and \$530,361 in stock-based compensation expense for the years ended December 31, 2017 and 2016, respectively, for the Company's stock option awards.

The following tables summarize the stock option activity for the year ended December 31, 2017:

	<b>Shares</b>		<b>Weighted Average Exercise Price</b>
Outstanding, December 31, 2016	113,672	\$	39.32
Granted	190,151	\$	7.88
Exercised		\$	
Forfeited/Expired	(37,013)	\$	20.18
Outstanding, December 31, 2017	266,810	\$	19.57

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2017 and 2016 was \$5.33 and \$12.84, respectively.

The following table summarizes information about stock options outstanding at December 31, 2017:

<b>Balance</b>	<b>Options Outstanding</b>		<b>Balance</b>	<b>Options Vested and Exercisable</b>	
	<b>Weighted</b>	<b>Weighted</b>		<b>Weighted</b>	<b>Weighted</b>
<b>as of</b>	<b>Average</b>	<b>Average</b>	<b>as of</b>	<b>Average</b>	<b>Average</b>
<b>12/31/2017</b>	<b>Remaining</b>	<b>Exercise</b>	<b>12/31/2017</b>	<b>Remaining</b>	<b>Exercise</b>
	<b>Contractual</b>	<b>Price</b>		<b>Contractual</b>	<b>Price</b>
	<b>Life</b>			<b>Life</b>	

266,810	(Years) 7.97	\$19.57	105,102	(Years) 6.07	\$36.28
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As of December 31, 2017, the unrecognized stock-based compensation expense related to unvested stock options was approximately \$2.2 million that is expected to be recognized over a weighted average period of approximately 16.7 months.

Total stock-based compensation expense including restricted stock, stock options, and common stock was \$689,130 and \$582,630 for the years ended December 31, 2017 and 2016, respectively.

## 10.

### *Income Tax*

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

	<b>Years ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Current expense:		
Federal	\$	\$
State		
Foreign		
Deferred expense (benefit):		
Federal	\$ (762,580)	\$
State	(46,960)	
Total	\$ (809,540)	\$

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

On December 22, 2017, the Tax Cuts and Jobs Act (the Act) was enacted into law. The Tax Act lowered the Federal corporate tax rate from 34% to 21% for periods beginning on or after January 1, 2018 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. The Company is required to recognize the effect of tax law changes in the period of enactment. Additional federal and state interpretive guidance is still forthcoming that could potentially affect the measurement of these balances or give rise to new deferred tax amounts. As such, the remeasurement of our deferred tax balance is provisional pending future guidance. The Company reasonably anticipates that any such guidance will be available prior to December 31, 2018.

Further, as part of the acquisition of Pelican, indefinite-lived intangibles were included for in-process R&D. This results in a deferred tax liability as there is no tax basis for these intangibles. Indefinite-lived intangibles are not available to offset deferred tax assets for purposes of determining any needed valuation allowance. Therefore, the valuation allowance was applied only to the definite-lived deferred tax assets and liabilities resulting in a net deferred tax liability position.

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

	<b>Years ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
Federal income tax expense at statutory rate	\$ (4,495,000)	\$ (4,411,000)
Increase (reduction) in income tax resulting from:		
State and local income taxes, net of federal benefit	(194,000)	69,000
Foreign rate differential	16,000	(18,000)
Non-deductible expenses	9,000	8,000
Prior-period true-up		547,000
Research & development credit	(409,000)	(575,000)
Stock-based compensation	84,000	113,000
Acquisition costs	96,000	
Reserve for loss carryforwards limited by Sec. 382	(541,000)	
Tax reform impact	8,024,000	
Other	45,460	(1,000)
Increase in valuation allowance	(3,445,000)	4,268,000
	\$ (809,540)	\$

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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, 2017 and December 31, 2016:

	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Deferred tax assets:		
Net operating loss carryforward	\$ 15,117,487	\$ 19,303,020
Research & development credit	1,966,964	1,557,475
Stock-based compensation	629,447	838,297
Contingent consideration	599,343	
Other	128,522	203,661
Deferred tax assets	18,441,763	21,902,453
Deferred tax liabilities:		
Property, plant and equipment, primarily due to differences in depreciation	(26,307)	(41,953)
Intangible assets	(1,302,220)	
Deferred tax liabilities:	(1,328,527)	(41,953)
Valuation allowance	(18,415,456)	(21,860,500)
Net deferred income taxes	\$ 1,302,220	\$

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**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

On April 28, 2017, the Company acquired 80% of the stock of Pelican. The company has integrated Pelican into the 12/31/17 provision including all current year activity, NOLs, and credit carryforwards. A deferred tax liability was created and booked to the trial balance during the transaction with the creation of intangible assets that will not have tax basis. Costs incurred during the transaction have been deemed as either facilitative or success based and accounted for under the guidance of IRS §1.263(a) and Rev. Proc. 2011-29.

At December 31, 2017 and December 31, 2016, 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 decreased from \$21,860,500 at December 31, 2016 to \$18,415,456 at December 31, 2017. The decrease in valuation allowance was due primarily to the decrease in future federal tax rate from 34% to 21%.

At December 31, 2017, the Company has federal net operating loss carryforwards of \$68,272,110 including \$3,119,000 acquired from Pelican, 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 NOL of \$2,238,822. The federal net operating loss carryforwards begin to expire in 2029. The Company has various state net operating loss carryforwards totaling \$63,085,859, including \$2,922,000 from Pelican, 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 \$98,886. The foreign net operating loss carryforwards are carried forward indefinitely. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, state, and foreign income tax authorities.

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the consolidated financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered more-likely-than-not that the position taken will be sustained by a taxing authority. As of December 31, 2017 and 2016, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of operations. As of December 31, 2017 and 2016, the Company had no such accruals.

The Company files income tax returns in the United States and various state and foreign jurisdictions. The Company is subject to examination by taxing authorities for the tax years ended December 31, 2008 through 2016.

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. U.S. GAAP requires companies 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 may be adjusted during 2018 when additional information is obtained. Additional information that may affect our provisional amounts would include further clarification and guidance on how the Internal Revenue Service will implement the Tax Act, including guidance with respect to guidance on how state taxing authorities will implement tax reform and the related effect on our state income tax returns, completion of our 2017 tax return filings, and the potential for additional guidance from the Financial Accounting Standards Board related to the Tax Act.

***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.

**HEAT BIOLOGICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

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

**11.**

***Related Party Transactions***

The Company compensates its board members. Board members received between approximately \$77,000 and \$242,000 and \$61,000 and \$118,000, for services rendered during 2017 and 2016, respectively.

The Company acquired 80% of the outstanding equity of Pelican, a related party, during the year ended December 31, 2017, see Note 3.

The Company had a related party receivable balance of \$0 and \$103,017 as of December 31, 2017 and 2016, respectively. This related party receivable reflects a percent of labor that the Company's former Chief Scientific Officer, Dr. Schreiber performed on behalf of the Company's former subsidiary Pelican during 2016.

**12.**

***Net Loss Per Share***

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

For the years ended December 31, 2017 and 2016, all of the Company's common stock options and warrants are anti-dilutive and therefore have been excluded from the diluted calculation.

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

	<b>For the years ended</b>	
	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Net loss	\$ (12,409,866)	\$ (12,974,799)
Net loss - Non-controlling interest	(568,195)	(400,847)
Net loss attributable to Heat Biologics, Inc.	\$ (11,841,671)	\$ (12,573,952)
Weighted-average number of common shares used in net loss per share attributable to common stockholders - basic and diluted	3,845,342	1,758,621
Net loss per share attributable to Heat Biologics, Inc - basic and diluted	\$ (3.08)	\$ (7.15)

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

	<b>For the years ended</b>	
	<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>
Outstanding stock options	266,810	113,672
Unvested restricted stock units	21,779	5,625
Outstanding common stock warrants	310,397	310,397



**HEAT BIOLOGICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)****13.*****Commitments and Contingencies***

During 2014, the Company entered into a five-year lease for a total of 5,979 square feet. The Company believes that such facilities are adequate for our current operations, and that there are spaces available sufficient for any future expansion requirements should the need arise. Rent expense was \$226,001 and \$259,050, for the years ended December 31, 2017 and 2016, respectively. In 2018, Pelican entered into a five-year lease for a total of 5,156 square feet. The Company anticipates occupancy by March 2018. The Company's approximate future minimum payments for its operating lease obligations that have initial remaining non-cancelable terms in excess of one year are as follows:

<b>Years ending December 31,</b>	
2018	324,551
2019	309,729
2020	115,580
2021	118,158
2022	120,736
Thereafter	20,194
<b>Total</b>	<b>\$ 1,008,948</b>

**14.*****Subsequent Events***

On January 18, 2018, the Company entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC as sales agent, pursuant to which the Company may sell from time to time, at its option, shares of its common stock, par value \$0.0002 per share for the sale of up to \$3,658,000 of shares of the Company's common stock.

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